SBF-CM

Folder Details

Folder ID: 127477 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 06/01/2013
Received: 5/22/2013
Date Sent: 8/26/2013

Security: A-AES
Response:

Abstract: Watson 2013 procurement quota increase request for oxycodone (b)(4);(b)(7)(E)

Signature: J. Rannazzisi

Doc Categories:

Doc Types: Memo

(b)(6);(b)(7)(C)	ODG	05/29/2013	8/26/2013

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: 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

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

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 Coordinator
Regulatory Unit - ODGR

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

Memorandum

Subject	Date
Watson (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	MAY 2 2 2013

To	From
Barbara Boockholdt Chief Regulatory Section Office of Diversion Control	Christine A. Sannerud, Ph.D. Chief UN Reporting and Quota Section Office of Diversion Control

Background:

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

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

Ref LtR (b)(7)(E) 5

SBF-CM

Folder Details

Folder ID: 127747 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 06/16/2013
Received: 6/6/2013
Date Sent: 8/27/2013

Security: A-AES
Response:
Abstract: Caraco Pharma Labs 2013 procurement quota increase request oxycodone (b)(4);(b)(7)(E)
Signature: C. Sannerud
Doc Categories:
Doc Types: Memo

(b)(6);(b)(7)(C)	ODG	06/13/2013	6/14/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

4/16/2015 2:33:32 PM

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

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, 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

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

Memorandum

Subject	Date
Caraco Pharma Labs (DEA# (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	JUN 6 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of 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 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.

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

LIR, (b)(7)(E) 5

SBF-CM

Folder Details

Folder ID: 127748 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 06/16/2013
Received: 6/6/2013
Date Sent: 8/27/2013

Security: A-AES **Response:**

Abstract: Watson Laboratories Inc 2013 procurement quota increase request for oxycodone (b)(4);(b)(7)(E)

Signature: C. Sannerud

Doc Categories: **Doc Types:** Memo

(b)(6);(b)(7)(C)	ODG	06/13/2013	6/14/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

IN SBF-CM

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

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

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

Memorandum

Subject	Date
Watson Laboratories, Inc. (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	JUN 6 2013

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 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.

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

Full customer list sent electronically.

REF. LTR (b)(7)(E)

SBF-CM

Folder Details

Folder ID: 127586 **Reg No:** (b)(7)(E)

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

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	06/21/2013	6/24/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

Memorandum

Subject	Date
Amneal Pharmaceuticals of New York, LLC (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	JUN 14 2013

To	From
Barbara Boockholdt Chief Regulatory Section Office of Diversion Control	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 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)

From: (b)(6);(b)(7)(C)
Sent: Friday, June 21, 2013 11:46 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 14, 2013

Importance: High

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

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.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Amneal Pharmaceuticals of New York, LLC (b)(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 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.

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

SBF-CM

Folder Details

Folder ID: 127884 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 06/24/2013
Received: 6/14/2013
Date Sent: 4/16/2015

Security: A-AES
Response:

Abstract: Amneal Pharmaceuticals of New York LLC (b)(4);(b)(7)(E)
2013 Procurement quota increase for oxycodone

Signature: Christine Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C) ODG 06/21/2013 6/26/2013

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: Friday, June 21, 2013 11:49 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 14, 2013

Importance: High

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

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.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Amneal Pharmaceuticals of New York, LLC (b)(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 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.

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

Memorandum

Subject	Date
Amneal Pharmaceuticals of New York, LLC (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	JUN 14 2013

To	From
Barbara Boockholdt Chief Regulatory Section Office of Diversion Control	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 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.

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: Tuesday, June 11, 2013 8:30 AM
To: (b)(6);(b)(7)(C) @amneal.com
Subject: 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: **Customer Name**, **Customer DEA Registration #**, **Total Sales quantity to Customer as base in kg (not dosage quantities)**. 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

SBF-CM

Folder Details

Folder ID: 126856 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 08/15/2013
Received: 8/5/2013
Date Sent: 4/16/2015

Security: A-AES **Response:**

Abstract: Amerisource Health Services Corp
(b)(4);(b)(7)(E)
2013 PQ Increase Request for oxycodone

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

Doc Categories: **Doc Types:** Memo

(b)(6);(b)(7)(C)	ODG	08/12/2013	8/14/2013

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: RE: Quota Increase Request Received on August 7, 2013

Importance: High

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

On August 7, 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

American Health Services Corporation (AHSC) (b)(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) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Columbus District Office, who stated that there are no investigative actions pending that would prevent AHSC 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) 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*

Memorandum

Subject	Date
Amerisource Health Service Cor (DEA# (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	AUG 5 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of 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.

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

SBF-CM

Folder Details

Folder ID: 128888 **Reg No:** (b)(7)(E)

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

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)

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C) ODG 08/12/2013 8/19/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

Memorandum

Subject	Date
Watson Labs (DEA# (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	AUG 5 2013

To	From
Barbara Boockholdt Chief Regulatory Section Office of Diversion Control	Christine A. Sannerud, Ph.D. Chief UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone/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.

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

(b)(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, 2013 1:11 PM
To: (b)(6);(b)(7)(C)
Subject: RE: Quota Increase Request Received on August 7, 2013
Importance: High

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

On August 7, 2013 this section received your request to review one (1) quota increase application from Watson Laboratories, Inc. 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

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 August 16, 2013, Staff Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Riverside, CA. District Office who stated that there are no investigative actions pending that would prevent Watson 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) 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)
Staff Coordinator
Regulatory Unit - ODGR
(b)(6);(b)(7)(C)
E-mail: (b)(6);(b)(7)(C) @usdoj.gov

Ref Letter (b)(7)(E)

5

SBF-CM

Folder Details

Folder ID: 128590 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 08/15/2013
Received: 8/5/2013
Date Sent: 8/26/2013

Security: A-AES
Response:
Abstract: Amneal Pharma 2013 procurement quota increase reuqest oxycodone
Signature: (b)(6);(b)(7)(C)
Doc Categories:
Doc Types: Memo

(b)(6);(b)(7)(C)	ODG	08/12/2013	8/26/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

Memorandum

Subject	Date
Amneal Pharma (DEA# (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	AUG 5 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of 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.

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: Wednesday, August 14, 2013 9:05 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 August 7, 2013

Importance: High

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

On August 7, 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

Amneal Pharmaceuticals of New York, LLC (b)(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) (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)(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*

SBF-CM

Folder Details

Folder ID: 128587 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 08/15/2013
Received: 8/5/2013
Date Sent: 4/4/2014

Security: A-AES **Response:**

Abstract: Vintage Pharmaceuticals, LLC
(b)(4);(b)(7)(E)
2013 PQ Increase Request for hydrocodone and oxycodone

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

Doc Categories: **Doc Types:** Memo

(b)(6);(b)(7)(C) ODG 08/12/2013 8/26/2013

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, August 15, 2013 1:04 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 August 7, 2013

Importance: High

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

On August 7, 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

Vintage Pharmaceuticals, LLC (Vintage) (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, LLC (Vintage).

(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 15, 2013, Staff Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Birmingham Resident Office, who stated that there are no investigative actions pending that would prevent Vintage from receiving an increase in quota for Oxycodone or Hydrocodone. GS (b)(6);(b)(7)(C) said that Vintage is a very responsible company, and that she is on the telephone with them daily. It should be noted that Vintage has one of the largest, if not the largest, customer base of any DEA manufacturer.

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 (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)
Staff Coordinator
Regulatory Unit - ODGR
(b)(6);(b)(7)(C)
E-mail: (b)(6);(b)(7)(C) *@usdoj.gov*

Memorandum

Subject	Date
Vintage #(b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone / Oxycodone (DFN: 630-08.2)	AUG 5 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of hydrocodone 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.

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

Ref Ltr (b)(7)(E)

SBF-CM

Folder Details

Folder ID: 128854 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 08/17/2013
Received: 8/7/2013
Date Sent: 8/27/2013

Security: A-AES
Response:

Abstract: (b)(4)
(b)(4);(b)(7)(E)
2013 PQ Increase Request for hydrocodone (DNF 630-08.2)

Signature:

Doc Categories:

Doc Types: Memo

(b)(6);(b)(7)(C) ODG 08/14/2013 8/22/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

DW SBF Cm

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

From: (b)(6);(b)(7)(C)
Sent: Wednesday, August 21, 2013 1:06 PM
To: Sannerud, Christine A.
Cc: Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
(b)(6);(b)(7)(C)

Subject: Review of (b)(4) (b)(4);(b)(7)(E) and Their Customers Per a Request from (b)(4) for an Increase in Their Procurement Quota

Attachments: Procurement Quota Increase Request Hydrocodone (b)(4) 08 07 2013.pdf

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

On August 13, 2013, ODGR received the attached Memorandum dated August 07, 2013, requesting a review of (b)(4) and their request for an increase in their Procurement Quota for 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 (b)(4) and their potential customers for Hydrocodone. Provided below are the results and recommendations of that inquiry.

(b)(4) is currently registered with DEA at (b)(4) as a Manufacturer (Re-packager/Re-Labeler) under DEA registration number (b)(4);(b)(7)(E) expiring July 31, 2014.

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

THE FOLLOWING CUSTOMERS OF (b)(4) ARE CURRENTLY UNDER REVIEW AND INVESTIGATION BY THE FIELD DIVISIONS WHERE THESE REGISTRANTS ARE LOCATED:

(b)(4);(b)(7)(E)	06/30/2015
(b)(4);(b)(7)(E)	01/31/2014
(b)(4);(b)(7)(E)	06/30/2014
(b)(4);(b)(7)(E)	06/30/2015
(b)(4);(b)(7)(E)	03/31/2015

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) *@usdoj.gov*
(b)(6);(b)(7)(C) *(Business)*
(Blackberry)
(Fax)

Memorandum

Subject	Date
(b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	AUG 7 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D. /for
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.

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

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

AUG 13 2013

Completed
8/21/13
(b)(6);(b)(7)(C)

Drug Enforcement Administration

EXECUTIVE SECRETARIAT

CONTROL SHEET

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

AUTHOR: Ms (b)(6);(b)(7)(C)
Unit Chief
ODEQ
ODE

LOCATION: ODEQ

TO:

SECURITY: A-AES

DOC CATEGORIES:

DOC TYPE: Memo

DOC DATE:

DATE RECEIVED: 8/7/2013

DATE DUE: 08/17/2013

DATE CLOSED:

CREATED BY: (b)(6);(b)(7)(C) 8/7/2013

MODIFIED BY:

ABSTRACT: (b)(4)
(b)(4);(b)(7)(E
2013 PQ Increase Request for hydrocodone (DNF 630-08.2)

SIGNATURE:

NOTES:

FYI - INFO COPIES:

FOLDER PRIORITY: High Priority

Assignments

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

Requested Activity:

Ref Ltr (b)(7)(E)

S

SBF-CM

Folder Details

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 Procurement Quota Increase Request for hydrocodone

Signature:

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C) ODG 08/26/2013 8/22/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

IN - SBF Cat

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

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

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) *@usdoj.gov*
(b)(6);(b)(7)(C) *(Business)*
(Blackberry)
(Fax)

Memorandum

Subject	Date
Mikart, Inc. (b)(4);(b)(7)(E) 2013 2012 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	AUG 19 2013

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 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)

Ref LID (b)(7)(E) S

SBF-CM

Folder Details

Folder 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 Request for oxycodone

Signature: Christine A. Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)	ODG	08/20/2013	8/28/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

IW - SBF CM

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

From: (b)(6);(b)(7)(C)
Sent: Tuesday, August 27, 2013 2:45 PM
To: Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
(b)(6);(b)(7)(C)
Subject: Review of Activas (b)(4);(b)(7)(E) and Their Customers Per a Request from 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 two 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 (b)(4);(b)(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)

(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) *@usdoj.gov*
(b)(6);(b)(7)(C) *(Business)*
(Blackberry)
(Fax)

Memorandum

Subject	Date
Actavis (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	AUG 13 2013

To	From
Barbara Boockholdt Chief Regulatory Section Office of Diversion Control	Christine A. Sannerud, Ph.D. Chief UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 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 LID (b)(7)(E)

5

SBF-CM

Folder Details

Folder ID: 126828 **Reg No:** (b)(7)(E)

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

Addressed To:

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)	ODG	10/28/2013	11/4/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

In SBF-CM

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

To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (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) (b)(6);(b)(7)(C) to determine if KVK should receive an increase in quota for Oxycodone. DI also of the Philadelphia Field Division, sent SC (b)(6);(b)(7)(C) an e-mail on 10/29/2013, stating that he has no problems with KVK receiving an increase in quota for Oxycodone.

The Control Sheet will be returned to ODQ, with copies of SC (b)(6);(b)(7)(C) findings and DI (b)(6);(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 Coordinator
Regulatory Unit - ODGR
(b)(6);(b)(7)(C)
E-mail: (b)(6);(b)(7)(C) *@usdoj.gov*

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

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

From: (b)(6);(b)(7)(C)
Sent: Tuesday, October 29, 2013 8:01 AM
To: (b)(6);(b)(7)(C)
Cc:
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)(C)

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

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

Memorandum

Subject	Date
KVK-Tech, Inc. #(b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	OCT 2 1 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of 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)

OCT 2 1 REC'D

REF LTR (b)(7)(E) 5

SBF-CM

Folder Details

Folder ID: 129830 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 10/31/2013
Received: 10/21/2013
Date Sent: 11/4/2013

Security: A-AES **Response:**

Abstract: Vintage 2013 procurement quota increase request hydrocodone and oxycodone

Signature: (b)(4);(b)(7)(E)
C. Sannerud

Doc Categories: **Doc Types:**

(b)(6);(b)(7)(C)	ODG	10/21/2013	11/4/2013

Action: Recommendation and Comments
Requested Activity:
Response Notes: -Automatically closed by system when folder was closed

TN: SBF-CM

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

From: (b)(6);(b)(7)(C)
Sent: Thursday, October 31, 2013 1:12 PM
To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C)
Subject: RE: Quota Increase Request Received on October 23, 2013

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

On October 23, 2013 this section received your request to review two (2) quota increase applications from one (1) registered manufacturer, who distribute oxycodone and hydrocodone 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

Vintage Pharmaceuticals, LLC (Vintage) (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, LLC (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 October 30, 2013, Staff Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Birmingham, AL Resident Office who stated that there are no investigative actions pending that would prevent Vintage from receiving an increase in quota for Oxycodone or Hydrocodone. GS (b)(6);(b)(7)(C) said that Vintage is always looking to receive an increase in quota, and stated "I guess it is alright if they receive an increase".

(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 (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 and our investigation, 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

Memorandum

Subject	Date
Vintage (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	OCT 21 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:

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

Ref Ltr (b)(7)(E)

5

SBF-CM

Folder Details

Folder ID: 130112 **Reg No:** (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 11/18/2013
Received: 11/8/2013
Date Sent:
Response:

Security: A-AES
Abstract: Mikart 2013 procurement quota increase request for hydrocodone memo (b)(4);(b)(7)(E)
Signature: Christine Sannerud
Doc Categories:
Doc Types:

(b)(6);(b)(7)(C) ODG 11/29/2013
Action: Handle as appropriate.
Requested Activity: Sending document to ODQ on 11/15/2013 (b)(6);(b)(7)(C)
Response Notes:

(b)(6);(b)(7)(C) ODG 11/15/2013
Action: Recommendation and Comments
Requested Activity:
Response Notes:

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

From: (b)(6);(b)(7)(C)
Sent: Thursday, November 14, 2013 1:47 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 November 8, 2013

Importance: High

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

On November 8, 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

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

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

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

Based on the above findings, it is recommended that the increased amounts of Hydrocodone be reviewed to determine if they are warranted. (b)(6);(b)(7)(C)

On November 13, 2013, Staff Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Atlanta Division Office who was unavailable to return SC (b)(6);(b)(7)(C) voice message regarding Mikart, and 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 receiving a quota increase". A copy of the above e-mail will be included with the rest of SC (b)(6);(b)(7)(C) findings for this investigation. (b)(6);(b)(7)(C)

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 consideration of amounts should be assessed based on Mikart's volume of customers.

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

Memorandum

Subject	Date
Mikart (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	NOV 8 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine A. Sanhenud, 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 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.

2013 NOV -8 PM 12: 04