

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

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

(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

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

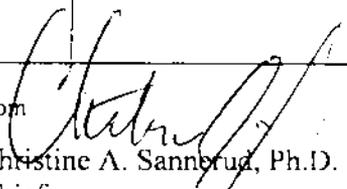
Date

MAY 22 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 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.

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

ILW SBF-CM
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

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

Date

JUN 6 2013

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From

Christine 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 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.

SBF-CM Folder Details

Folder ID: 127746

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

IIV SBF-CM
4/16/2015 2:30:04 PM

(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)

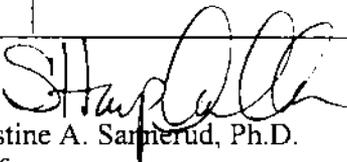
E-mail: (b)(6);(b)(7)(C) @usdoj.gov

Memorandum



Subject Watson Laboratories, Inc. (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	Date JUN 6 2013
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To
Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From 
Christine A. Samnerud, 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.

SBF-CM Folder Details

Folder ID: 127886

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 procurement 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

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

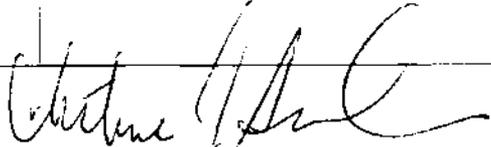
Date

JUN 14 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)

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

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

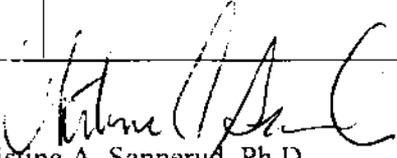
Date

JUN 14 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.

(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)@amreal.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: 120000

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

4/16/2015 2:42:08 PM

(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

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

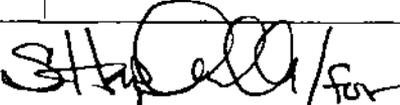
Date

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: 125859 **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
Response:

Security: A-AES

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

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

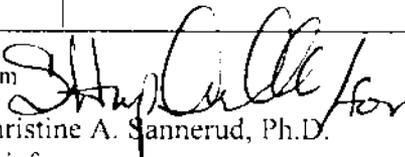
Date

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/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

SBF-CM Folder Details

Folder ID: 128800

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 request 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 Amneal Pharma (DEA# (b)(4):(b)(7)(E)) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	Date AUG 5 2013
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To
Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From *Steph Oll* /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 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: 128687

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

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

Date

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.

SBF-CM Folder Details

Folder ID: 43084 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
Abstract: (b)(4)
(b)(4);(b)(7)(E)

Response:
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

JW SBF CM
4/16/2015 2:58:30 PM

(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 <div data-bbox="143 304 720 348" style="border: 1px solid black; padding: 2px;">(b)(4);(b)(7)(E)</div> 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	Date AUG 7 2013
--	-------------------------------

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From *Stacy All* /for
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)

AUG 13 2013

Drug Enforcement Administration
 EXECUTIVE SECRETARIAT
 CONTROL SHEET

✓
 Completed
 8/21/13

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

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

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

DOC DATE:
 DATE 8/7/2013
 RECEIVED:

LOCATION: ODEQ
 TO:

DATE DUE: 08/17/2013
 DATE CLOSED:

SECURITY: A-AES
 CREATED BY: (b)(6);(b)(7)(C) 8/7/2013
 MODIFIED BY:

DOC CATEGORIES:

DOC TYPE: Memo

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:

SBF-CM Folder Details

Folder ID: 128418

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

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

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

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

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

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

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

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

(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)

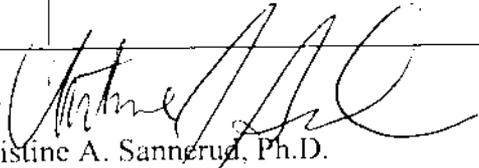
QC 13 2012 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

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)

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
4/16/2015 3:11:00 PM

(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 I.L.C. 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

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

Date

AUG 13 2013

To

Barbara Boeckholdt
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.

Per LID

(b)(7)(E)

5

SBF-CM Folder Details

Folder ID: 126829

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

IW SBF-CM
4/16/2015 3:19:52 PM

(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.

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

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) to determine if KVK should receive an increase in quota for Oxycodone. DI (b)(6);(b)(7)(C) 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)

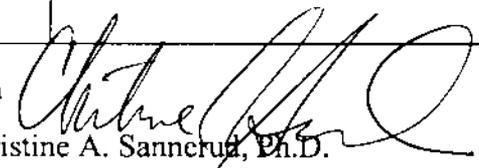
Got your msg but swamped with NTBI matters. Please contact (b)(6);(b)(7)(C) and DI (b)(6);(b)(7)(C) so that they can respond to you regarding KVK Tech. Thanks,

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

Memorandum



Subject KVK-Tech, Inc. # (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	Date OCT 21 2013
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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
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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 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 21 REC'D

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

EN- SBF-CM
4/16/2015 3:27:24 PM

(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, DIA 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 [redacted]

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

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

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

*Staff Coordinator
Regulatory Unit - ODGR*

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

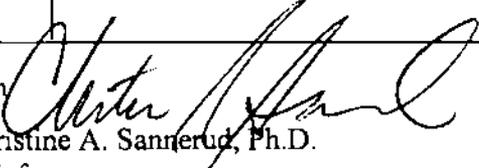
E-mail: (b)(6);(b)(7)(C) @usdoj.gov

Memorandum



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

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:

Security: A-AES

Response:

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 (b)(6);(b)(7)(C) was e-mailed by SC (b)(6);(b)(7)(C) 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.

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)

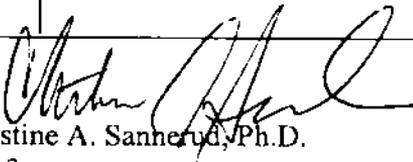
E-mail: (b)(6);(b)(7)(C) @usdoj.gov

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. 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.

2013 NOV - 8 PM 12:04