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

1

(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 1

(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

1

(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

4/16/2015 2:30:04 PM 1

(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

1

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

1

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

1

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*