

Ref LTR

(b)(7)(E)

5

### SBF-CM Folder Details

Folder ID: 126252

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

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

Addressed To:

Location: ODEQ  
Due: 03/24/2013  
Received: 3/14/2013  
Date Sent:

Security: A-AES

Response:

Abstract: (b)(4);(b)(7)(E)

Signature: 2013 procurement quota increase request for oxycodone  
Christine Sannerud

Doc Categories:

Doc Types:

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

ODG

03/21/2013 3/27/2013

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, March 21, 2013 3:20 PM  
**To:** (b)(6);(b)(7)(C); (b)(6);(b)(7)(C) Sannerud, Christine A.  
**Cc:** Boockholdt, Barbara J.; (b)(6);(b)(7)(C); (b)(6);(b)(7)(C)  
**Subject:** RE: Quota Increase Request Received on March 15, 2013  
**Importance:** High

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

On March 15, 2013 this section received your e-mail requesting a review of two (2) quota increase applications from two (2) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE 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**

Morton Grove Pharmaceuticals (b)(4);(b)(7)(E)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny a quota increase for Morton Grove Pharmaceuticals.

(b)(4);(b)(7)(E)  
Based on this information, ODG suggests that the increased quota be limited by a small percentage of the requested amount.

**QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION**

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

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

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

(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 <div style="border: 1px solid black; padding: 2px;">(b)(4);(b)(7)(E)</div> 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	Date  MAR 14 2013
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To  
  
Barbara Boockholdt  
Chief  
Regulatory Section  
Office of Diversion Control

From *Christine A. Samerud*  
Christine A. Samerud, 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, 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 establishing/revising the applicant's quota allocation for oxycodone.

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

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(b)(7)(E)

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### SBF-CM Folder Details

**Folder ID:** 126253

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

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

**Addressed To:**

**Location:** ODEQ

**Due:** 03/24/2013

**Received:** 3/14/2013

**Date Sent:**

**Response:**

**Security:** A-AES

**Abstract:** Morton Grove  
(b)(4);(b)(7)(E)

2013 Procurement Quota  
Increase Request for hydrocodone

**Signature:** Christine Sannerud

**Doc Categories:**

**Doc Types:**

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

ODG

03/21/2013 3/27/2013

**Action:** Recommendation and Comments

**Requested Activity:**

**Response Notes:** -Automatically closed by system when folder was closed

# Memorandum



Subject

Morton Grove (b)(4);(b)(7)(E)  
2013 Procurement Quota Increase Request  
Hydrocodone  
(DFN: 630-08.2)

Date

MAR 14 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 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.

### SBF-CM Folder Details

Folder ID: 127098

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

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

Addressed To:

Location: ODEQ  
Due: 05/10/2013  
Received: 4/30/2013  
Date Sent: 8/27/2013

Security: A-AES

Response:

Abstract: Kremers Urban Pharmaceuticals, Inc.  
(b)(4);(b)(7)(E)  
2013 Procurement Quota Increase Request  
Hydrocodone

Signature: Christine Sannerud

Doc Categories:

Doc Types:

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

ODG

05/07/2013 5/10/2013

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, May 09, 2013 2:48 PM  
**To:** (b)(6);(b)(7)(C); (b)(6);(b)(7)(C); Sannerud, Christine A.  
**Cc:** Boockholdt, Barbara J.; (b)(6);(b)(7)(C); (b)(6);(b)(7)(C)  
**Subject:** RE: Quota Increase Request Received on May 1, 2013  
**Importance:** High

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

On May 1, 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 ODE 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**

Kremers Urban Pharmaceuticals, Inc. (b)(4);(b)(7)(E)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny a quota increase for Kremers Urban Pharmaceuticals, Inc.

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

Based on this information, ODG suggests that the increased quota be limited by a small percentage of the requested amount.

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

Kremers Urban Pharmaceuticals, Inc.  
2013 Procurement Quota Increase Request  
Hydrocodone  
(DFN: 630-08.2)

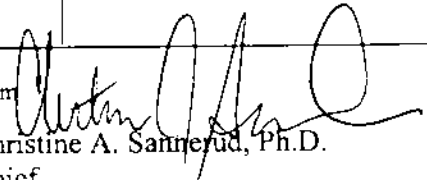
Date

APR 30 2013

To

Barbara Boockholdt  
Chief  
Regulatory Section  
Office of Diversion Control

From

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

## Background:

As a result of the recent increase in the diversion and abuse of hydrocodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains a customer list 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: 127094

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

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

Addressed To:

Location: ODEQ  
Due: 05/17/2013  
Received: 5/7/2013  
Date Sent: 8/26/2013

Security: A-AES

Response:

Abstract: KVK Tech, Inc. (b)(4);(b)(7)(E)  
2013 Procurement Quota Increase Request Oxycodone

Signature: Christine Sannerud

Doc Categories:

Doc Types: Memo

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

ODG

05/07/2013 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, May 16, 2013 11:13 AM  
**To:** (b)(6);(b)(7)(C); (b)(6);(b)(7)(C); Sannerud, Christine A.  
**Cc:** Boockholdt, Barbara J.; (b)(6);(b)(7)(C)  
**Subject:** FW: Quota Increase Request Received on May 7, 2013  
**Importance:** High

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

On May 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

KVK Tech, Inc.

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

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny a quota increase for KVK Tech, Inc.

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

Based on this information,

ODG suggests that the increased quota be approved.

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

KVK Tech, Inc (DEA# (b)(4);(b)(7)(E))  
2013 Procurement Quota Increase Request  
Oxycodone  
(DFN: 630-08.2)

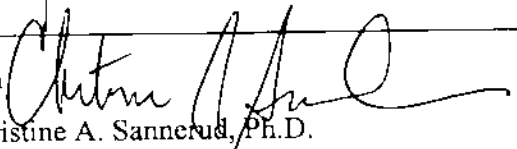
Date

APR 30 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 establishing/revising the applicant's quota allocation for oxycodone.

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

### SBF-CM Folder Details

Folder ID: 127351

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

Author: Sannerud, Christine A

Addressed To:

Location: ODEQ  
Due: 05/25/2013  
Received: 5/15/2013  
Date Sent: 8/26/2013

Security: A-AES

Response:

Abstract: Sovereign Pharmaceuticals 2013 procurement quota increase request for hydrocodone (b)(4);(b)(7)(E)

Signature: C. Sannerud

Doc Categories:

Doc Types:

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

ODG

05/22/2013 8/26/2013

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

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

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**From:** (b)(6);(b)(7)(C)  
**Sent:** Friday, May 24, 2013 11:08 AM  
**To:** (b)(6);(b)(7)(C)  
**Subject:** RE: Sovereign Pharmaceuticals, LLS (DEA# (b)(4);(b)(7)(E))

Not a problem

**From:** (b)(6);(b)(7)(C)  
**Sent:** Friday, May 24, 2013 7:17 AM  
**To:** (b)(6);(b)(7)(C)  
**Subject:** Sovereign Pharmaceuticals, LLS (DEA# (b)(4);(b)(7)(E))

Good Morning (b)(6);(b)(7)(C)

Do you have any problem with Sovereign receiving additional quota?

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

# Memorandum



Subject

Sovereign Pharmaceuticals, LLC (DEA#(b)(4):(b)(7)(E))  
2013 Procurement Quota Increase Request  
Hydrocodone  
(DFN: 630-08.2)

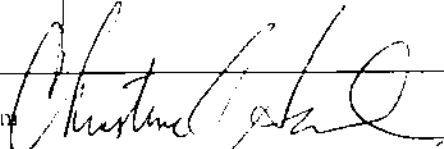
Date

MAY 15 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 the use of the internet to traffic 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 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.