Memorandum

Subject
Quota Letters Received as of December 20, 2010
(DFN: 630-08.2)

Date
JAN 04 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Broekholdt, Chief
Regulatory Section
Office of Diversion Control

On December 20, 2010, this section received your e-mail requesting a review of three (3) quota applications from two registered manufacturers to determine if there were 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
Mylan Chestnut Ridge Road, West Virginia (10920)

QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION
OSC/Settlement
Discussion Ongoing

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC

Vol. II Page 324
Memorandum

Subject
Quota Letters Received as of January 06, 2011
(DFN: 630-08.2)

Date

Jan 3 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 06, 2011, this section received your e-mail requesting a review of fifty-six (56) quota applications from forty-one (41) registered manufacturers to determine if there were 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 inputs and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Abbott Laboratories North Chicago (IPQ029)
Mylan Pharmaceuticals, Inc. (IPQ025)
Hisamitsu California Laboratories (IPQ148)
USP (10906)
Mylan (10905)
Almac (10908)
Cerilliant (10909)
Mylan (10913)
Mylan (10914)
DSM Pharmaceuticals (10948)
Mylan Pharmaceuticals (10949)
Mylan Pharmaceuticals (10950)
3M Drug Delivery Systems (10951)
Watson Laboratories, Inc. (10952)
Watson Laboratories, Inc. (10953)
United Liquid, Inc. (10954)
Emerson Resources Inc. (10955)
Tris Pharma, Inc. (10956)
Cody Labs (10973)
Mallinckrodt St. Louis (10974)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of January 13, 2011
(DFN: 630-08.2)

Date
JAN 18 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 13, 2011, this section received your e-mail requesting a review of twenty-two (22) quota
applications from nineteen (19) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

AAI Pharma (10987)
Cody Labs (10989)
Mallinckrodt St. Louis (10990)
Patheon Pharmaceuticals (10992)
Bio Pharm (10993)
Watson Laboratories, Inc. (10994)
Akorn, Inc. (10995)
Pharmaceutical Intl Inc. (10996)
Pharmaceutical Intl Inc. (10997)
Norac, Inc. (10998)
Aptuit, Inc. (10999)
Catalent Pharma Solutions (11000)
Restek (11002)
Watson Laboratories, Inc. (11004)
Watson Laboratories, Inc. (11005)
Mylan (11006)
Vintage Pharmaceuticals (11007)
Bio-Pharm, Inc. (11008)
Epic Pharma (11009)
Fisher Clinical (11010)
APP Pharmaceuticals (11011)
Baxter (11014)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of January 19, 2011
(DFN: 630-08.2)

Date
JAN 2 1 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 19, 2011, this section received your e-mail requesting a review of seventeen (17) quota
applications from fifteen (15) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Pii (11016)
Pii (11017)
Pii (11018)
Qualitest Pharmaceuticals (11019)
Metrics (11020)
Mallinckrodt (11021)
Neos Therapeutics, LP (11023)
AMRI Rensselear, Inc. (11024)
AMRI Rensselear, Inc. (11025)
KV Pharmaceuticals (11026)
KV Pharmaceuticals (11026) 2 of 2
King Pharmaceuticals (11036)
Catalent Pharma Solutions (11037)
Noramco (11038)
Penick (11039)
Glatt Air (11040)

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

Currently under OSC
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject
Quota Letters Received as of January 24, 2011
(DFN: 630-08.2)

Date
JAN 25 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 24, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from nine (9) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Sure Tech (11044)
- Sharp Corporation (11046)
- Mylan Pharmaceuticals (11047)
- RX Pharmaceuticals (11049)
- Penick (11051)
- Siegfried (11052)
- Siegfried (11053)
- Siegfried (11054)
- Siegfried (11055)
- AmeriSource Ohio (11056)
- AmeriSource Ohio (11057)
- PharmaForm (11058)
- ECI (11059)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject: Additional Quota Requests as of January 25, 2010 (DIN: 636-08.2)

Date: JAN 27 2010

To: Christine A. Samnerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From: Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 25, 2010, this section received your e-mail requesting a review of fourteen (14) quota applications from eleven (11) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODD 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

- Sharp Corporation (9619)
- Eisely Laboratories (9621)
- Noramco (9625)
- Micron Technologies, Inc. (9626)
- Salfcor (9627)
- Austin Pharma (9628)
- Sigma-Aldrich (9629)
- Eminent (9634)
- Siegfried (9635)
- Siegfried (9636)
- Siegfried (9637)
- Watson (9638)
- Watson (9639)
- AAIPharma (9640)

Per consultation with the field offices, ODA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODGR suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of January 28, 2011
(DFN: 630-08.2)

Date
JAN 31 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 28, 2011, this section received your e-mail requesting a review of five (05) quota applications 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

- KV Pharmaceutical (11063)
- Patheon (11064)
- Aptuit, Inc. (11065)
- Anesta (11066)
- AAI Pharma (11067)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of January 31, 2011
(DFN: 630-08.2)

Date
FEB 02 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 31, 2011, this section received your e-mail requesting a review of sixteen (16) quota applications from twelve (12) 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.

<table>
<thead>
<tr>
<th>QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fleming &amp; Co (11069)</td>
</tr>
<tr>
<td>King Pharmaceutical (11070)</td>
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<tr>
<td>Metrics (11071)</td>
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<tr>
<td>Watson (11072)</td>
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<tr>
<td>Watson (11072)(2 of 2)</td>
</tr>
<tr>
<td>Amneal Pharmaceuticals (11073)</td>
</tr>
<tr>
<td>Glatt Air (11074)</td>
</tr>
<tr>
<td>Metrics (11075)</td>
</tr>
<tr>
<td>Fisher Clinical Services (11076)(1 of 3)</td>
</tr>
<tr>
<td>Fisher Clinical Services (11076)(2 of 3)</td>
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<tr>
<td>Fisher Clinical Services (11076)(3 of 3)</td>
</tr>
<tr>
<td>TG United (11077)</td>
</tr>
<tr>
<td>Ameridose, LLC (11078) (1 of 2)</td>
</tr>
<tr>
<td>Ameridose, LLC (11078) (2 of 2)</td>
</tr>
<tr>
<td>Bilcare (11079)</td>
</tr>
<tr>
<td>Mallinckrodt St. Louis (11080)</td>
</tr>
</tbody>
</table>
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject

2011 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

Date

FEB 03 2011

To
Christine A. Sannerud, Ph.D, Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On January 31, 2011, this section received your memorandum requesting a review of customers list, specifically, 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.

ODGR conducted NADDIS and CSA reviews of approximately one hundred fifty-three (153) customers as well as on

The following derogatory information was found on the seven (7) below listed customers:

Retired 11/17/2010
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Order to Show Cause
Currently Under Review/Investigation
Currently Under Review/Investigation

DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the request submitted by for the quota increase.

If you have any questions pertaining to this information, please feel free to contact me or SC

Vol. II Page 336
Memorandum

Subject: Quota Letters Received as of February 3, 2011 (DFN: 630-08.2)

Date: FEB 03 2011

To: Christine A. Sannerud, Ph.D., Chief
    Drug & Chemical Evaluation Section
    Office of Diversion Control

From: Barbara J. Boockholdt, Chief
    Regulatory Section
    Office of Diversion Control

On February 3, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from ten (10) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Vortech (11084)
- PAR Pharmaceutical (11085)(1 of 2)
- PAR Pharmaceutical (11085)(2 of 2)
- Pharmaceutics International, Inc. (11086)
- Pharmaceutics International, Inc. (11087)
- Pharmaceutics International, Inc. (11088)
- Nexgen Pharma, Inc. (11089)
- Tris Pharma, Inc. (11090)
- Ameridose, LLC (11078)(2 of 2)
- Rx Pak (11092)
- Pharmaceutics International, Inc. (11093)
- Catalent Pharma Solutions (11094)

QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

- Currently Under Review/Investigation

Vol. II Page 337
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject: Quota Letters Received as of February 10, 2011
(DFN: 630-08.2)

Date: FEB 14 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Bockholdt, Chief
Regulatory Section
Office of Diversion Control

On February 10, 2011, this section received your e-mail requesting a review of twenty-six (26) quota applications from twenty-five (25) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Cima Brooklyn Park (11099)
Johnson Matthey (11100)
Cephalon, Inc. (11101)
Siegfried (11102)
Mylan Chestnut Ridge Road, West Virginia (11103)
Upsher-Smith (11104)
PrePak Systems (11105)
Impax Pennsylvania (11106)
Impax Pennsylvania (11106)(2 of 2)
Watson (11107)
Watson (11107)(2 of 2)
Nexgen Pharma, Inc. (11108)
University of Mississippi (11109)
Bilcare (11111)
Patheon (11112)
Patheon (11113)
Elan Holdings (11114)
Epic Pharma (11115)
Actavis South-Atlantic (11116)
Cambrex (11117)
Mylan Technologies (11118)
Sandoz (Geneva Pharmaceuticals, Inc) (11119)
Novartis Consumer Health Lincoln (11120)
King Pharmaceuticals (11121)
Mallinckrodt St. Louis (11122)
Chattem (11123)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject
Quota Letters Received as of February 15, 2011
(DFN: 630-08.2)

Date
FEB 16 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On February 15, 2011, this section received your e-mail requesting a review of twenty-six (26) quota applications from eleven (11) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Fisher Clinical Services (11125)
- Fisher Clinical Services (11126)
- Barr Labs (11127)
- Cambrex (11128)
- AA1 Pharma Services (11129)
- Sigma-Aldrich Services (11130)
- Sigma-Aldrich Services (11131)
- Specialty Compounding (11132)
- Specialty Compounding (11133)
- Specialty Compounding (11134)
- Specialty Compounding (11136)
- Specialty Compounding (11137)
- Specialty Compounding (11138)
- Specialty Compounding (11139)
- Specialty Compounding (11140)
- Specialty Compounding (11141)
- Pfizer Pharmaceuticals (11143)
- Johnson Matthey (11145)
- Johnson Matthey (11146)
- Johnson Matthey (11147)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of February 17, 2011
(DFN: 630-08.2)

Date
FEB 23 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On February 17, 2011, this section received your e-mail requesting a review of fifteen (15) quota applications from fourteen (14) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Barr Laboratories (11154)
Norwich Pharmaceuticals (11155)
Pharmedium (11156)
Pharmedium (11157)
Qualitest Pharmaceuticals (11158)
Catalent Pharma Solutions (11159)
PD-RX Pharmaceuticals (11160)
Alltech Associates (11163)
Aurolife Pharma LLC (11164)
Fisher Clinical Services (11165)
Johnson Matthey (11166)
Fisher Clinical Services (11170)
Gallipot (11171)
Abbott Laboratories North Chicago (11172)
Tedor Pharma Inc (11173)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Request as February 25, 2011 (DFN: 630-08.2)

Date
March 4, 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On February 25, 2011, this section received your e-mail requesting a review of fifteen (15) 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. An incorrect DEA number was assigned to Log In #11175, the correct DEA number is [b](4)(b)(7)(E) Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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<tr>
<th>Log In #</th>
<th>Company Name</th>
<th>Registration #</th>
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<tbody>
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<td>11174</td>
<td>Alere San Diego</td>
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</tr>
<tr>
<td>11175</td>
<td>Qualitest</td>
<td></td>
</tr>
<tr>
<td>11176</td>
<td>Fisher Clinical Services</td>
<td></td>
</tr>
<tr>
<td>11177</td>
<td>Almac Clinical Services</td>
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<tr>
<td>11178</td>
<td>GSMS</td>
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</tr>
<tr>
<td>11180</td>
<td>Mallinckrodt St. Louis</td>
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<tr>
<td>11181</td>
<td>ANI Pharmaceuticals, Inc.</td>
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<td>11183</td>
<td>OHM Labs</td>
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<td>11184</td>
<td>Corium</td>
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<td>11186</td>
<td>Sure-Tech</td>
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<td>11187</td>
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<td>11188</td>
<td>Nexgen Pharma, Inc.</td>
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<tr>
<td>11189</td>
<td>DPT Paco Way</td>
<td></td>
</tr>
</tbody>
</table>
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact [redacted]

Cc: ChristineASannert, PhD/Chief/ODE/Drug&Chemical Evaluation Section
Cc: ODG
Cc: ODGR

The correct registration number for Qualitest (AKA Vintage) is

Hello

The above named registrant DEA number is incorrect, could not find DEA number is CSA. Please supply correct DEA number for review. Thank you.

Program Analyst
Regulatory Unit - ODGR

E-mail: @usdoj.gov
Good Morning,

Below is a list of quota applications from DEA-registered manufacturers received as of February 25, 2011.

We request that ODG and ODP review for pending administrative/legal action against these applicants and advise ODE of your findings.

Thank you in advance.

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Registration #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alere San Diego</td>
<td>(b)(6);(b)(7)(E)</td>
</tr>
</tbody>
</table>
11175 Qualitest
11176 Fisher Clinical Services
11177 Almac Clinical Services
11178 GSMS
11180 Mallinckrodt St. Louis
ANI Pharmaceuticals, Inc.
11181 OLM Labs
11183 Conium
11184 Sure-Tech
11185 Archimica
11188 Nexgen Pharma, Inc.
11189 DPT Paco Way
11190 Siegfried
11191 Siegfried

Program Analyst
Quota Unit (ODEQ)
Drug & Chemical Evaluation Section
Office of Diversion Control
Memorandum

Subject
Quota Request as February 28, 2011
(DFN: 630-08.2)

Date
MAR 04 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On February 28, 2011, this section received your e-mail requesting a review of seven (7) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

<table>
<thead>
<tr>
<th>Log In #</th>
<th>Company Name</th>
<th>Registration #</th>
</tr>
</thead>
<tbody>
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<td>11193</td>
<td>KVK Tech, Inc.</td>
<td>(b)(4),(b)(7)(E)</td>
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<tr>
<td>11194</td>
<td>Mylan Pharmaceuticals</td>
<td></td>
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<tr>
<td>11195</td>
<td>Mylan Pharmaceuticals</td>
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<td>11196</td>
<td>Siegfried PD-RX</td>
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<td>11211</td>
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<tr>
<td>11213</td>
<td>Fisher Clinical</td>
<td></td>
</tr>
</tbody>
</table>

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact Chief/ODGR at [b](6):[b](7):[C]
From: Boockholdt, Barbara J.
Sent: Tuesday, March 01, 2011 7:51 AM
To: Boockholdt, Barbara J.
Cc: Sannerud, Christine A.; Hill, Robert L.
Subject: FW: Quota Letters Received as of February 28, 2011

See attached quota request.

Thanks!

Chief, Regulatory Unit/ODGR
DEA Headquarters

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From: Boockholdt, Barbara J.
Sent: Monday, February 28, 2011 5:04 PM
To: Boockholdt, Barbara J.
Cc: Sannerud, Christine A.; Hill, Robert L.
Subject: Quota Letters Received as of February 28, 2011

Good Afternoon,

Below is a list of quota applications from DEA-registered manufacturers received as of February 28, 2011.

We request that ODG and ODP review for pending administrative/legal action against these applicants and advise ODE of your findings.

Thank you in advance.
<table>
<thead>
<tr>
<th>Log in #</th>
<th>Company Name</th>
<th>Registration #</th>
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<tbody>
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<td>11193</td>
<td>KVK Tech, Inc.</td>
<td>(b)(4),(b)(7)(E)</td>
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<td>11194</td>
<td>Mylan Pharmaceuticals</td>
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<td>11195</td>
<td>Mylan Pharmaceuticals</td>
<td></td>
</tr>
<tr>
<td>11196</td>
<td>Siegfried PD-RX Pharmaceuticals</td>
<td></td>
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<tr>
<td>11211</td>
<td>Penick Corp</td>
<td></td>
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<tr>
<td>11213</td>
<td>Fisher Clinical</td>
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</tr>
</tbody>
</table>

Program Analyst
Quota Unit (ODEQ)
Drug & Chemical Evaluation Section
Office of Diversion Control
Subject
Quota Letters Received as of March 3, 2011
(DFN: 630-08.2)

Date
MAR 09 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boekholdt, Chief
Regulatory Section
Office of Diversion Control

On March 3, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Halo Pharmaceutical Company (11215)
Norac Inc (11216)
Axcentra (11220)
Ortho McNeil Pharmaceutical (11221)
Hospira, Inc. NC (11222)
Impax Pennsylvania (11223)
Archimica (11225)
Anderson Packaging, Inc (11226)
Aurolife Pharma (11227)
Coating Place Inc (11228)
Cerilliant (11229)
Watson (11230)
Cody Labs (11231)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject
Quota Letters Received as of March 7, 2011
(DFN: 630-08.2)

Date
MAR 09 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On March 7, 2011, this section received your e-mail requesting a review of five (05) quota applications to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Patheon (11182)
- Hisamitsu California Laboratories (11232)
- Johnson Matthey (11233)
- Cambrex (11234)
- Cody Laboratories (NA001)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of March 11, 2011
(DFN: 630-08.2)

Date
MAR 14 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On March 11, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from twelve (12) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Barr Laboratories (11241)
Mylan Chestnut Ridge Road, West Virginia (11242)
Fisher Clinical Services (11244)
Glatt Air (11245)
Cima Brooklyn Park (11246)
Par Pharmaceutical (11247) (1 of 2)
Par Pharmaceutical (11247) (2 of 2)
Reckitt Benckiser (11248)
Lannett (11249)
Lannett (11249) (2 of 2)
Norwich Pharmaceuticals (11250)
Barr Laboratories (11251)
Bryant Ranch Prepack (11253)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of March 18, 2011
(DFN: 630-08.2)

Date
MAR 25 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Bookholdt
Barbara J. Bookholdt, Chief
Regulatory Section
Office of Diversion Control

On March 18, 2011, this section received your e-mail requesting a review of thirty-seven (37) quota applications from thirty-four (34) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Barr Labs (11260)
Purdue (11261)
Janssen Puerto Rico (11262)
Watson Labs (11263)
Alliance Contract Pharma (11264)
Novel Laboratories (11266)
Novel Laboratories (11267)
Pharmedium Cleveland (11268)
Pharmedium Cleveland (11270)
Safeer Health, LLC (11271)
Pisgah Labs Inc (11273)
Abbott Laboratories North Chicago (11274)
Cody Labs (11275)
Cima Brooklyn Park (11276)
AmeriSource Ohio (11277)
Cedarburg (11279)
Acura Pharmaceutical Technologies (11280)
Biochemical Diagnostics (11282)
Catalent Pharma Solutions (11283)
Catalent Pharma Solutions (11284)
Patheon (11285)
Vintage Pharmaceuticals (11286)
Vintage Pharmaceuticals (11287)
Vintage Pharmaceuticals (11288)
Halo Pharmaceutical Company (11289)
Pharmaceutics Intl Inc (11290)
Pharmaceutics Intl Inc (11290) (2 of 2)
Alvogen (11291)
Alvogen (11292)
Alvogen (11293)
DSM (11294)
Wildlife (11297)
Sun Pharmaceutical Industries (11298)
Cima Brooklyn Park (>4^96)
Cayman Chemical (11300)
Alaunus Pharmaceutical, Inc. (11301)
Mallinckrodt St. Louis (11302)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject
Quota Request as March 24, 2011
(DFN: 630-08.2)

Date
MAR 28 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On March 24, 2011, this section received your e-mail requesting a review of fifteen (15) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Aptuit, Inc. (11306)
Mylan Chestnut Ridge Road, West Virginia (11307)
Novartis Consumer Health Lincoln (11310)
Novartis Consumer Health Lincoln (11311)
Cerilliant (11312)
Janssen Puerto Rico (11313)
Alza Vacaville (11314)
Biochemical Diagnostics, Inc (11315)
Sun Pharmaceutical (11316)
Cambrex (11320)
Fisher Clinical (11321)
Siegfried (11323)
Metrics (11324)
Neos Therapeutics, LP (11325)
Novel Laboratories (11326)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.
If you have any questions pertaining to this information, please feel free to contact Chief/ODGR at [redacted].
Memorandum

Subject: Quota Letters Received as of March 28, 2011 (DFN: 630-08.2)

Date

MAR 29 2011

To

Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From

Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On March 28, 2011, this section received your e-mail requesting a review of seven (07) quota applications with six (6) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Baxter (11330)
Johnson Matthey (11331)
Johnson Matthey (11332)
Pharmacia & Upjohn (11333)
Aptuit, Inc. (11334)
Amneal - Hauppage (11335)
ANI Pharmaceuticals, Inc. (11336)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC
Memorandum

Subject: Quota Request as April 1, 2011
(DFN: 630-08.2)

Date: APR 06 2011

To:
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From:
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On April 1, 2011, this section received your e-mail requesting a review of fifteen (15) quota applications with thirteen (13) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

UCB Manufacturing (11338)
Vintage Pharmaceuticals (11339)
Norac (11340)
Medisca (11341)
AAI Pharma 1726 N. 23rd St (11342)
Norwich Pharmaceuticals (11343)
AmeriSource Ohio (11344)
Cambrex (11347)
3M 3M Center (11348)
Boehringer Ingelheim (11350)
Neos Therapeutics, LP (11351)
Akorn (11352)
Bienheim Pharmacal (11353)
Bienheim Pharmacal (11354)
Neos Therapeutics, LP (11355)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact the Chief/ODGR at [b](6) ; (b)(7)(C).
Memorandum

Subject
Quota Letters Received as of April 7, 2011
(DFN: 630-08.2)

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On April 7, 2011, this section received your e-mail requesting a review of nine (09) quota applications with eight (08) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

P F Laboratories (11382)
Purdue (11383)
Purdue (11384)
Siegfried (11385)
Tris Pharma, Inc (11396)
Halo Pharmaceutical Company (11387)
Sandoz (11388)
Actavis South Atlantic (11389)
Clinical Supplies Mgmt (11390)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject: Quota Letters Received as of April 18, 2011 (DFN: 630-08.2)

Date: APR 15 2011

To: Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From: Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On April 18, 2011, this section received your e-mail requesting a review of thirty-three (33) quota applications from twenty-five (25) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

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<th>Company Name</th>
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<td>Mylan Technologies</td>
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QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

Currently Under Investigation

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of April 26, 2011
(DFN: 630-08.2)

Date
APR 28 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Blockholdt, Chief
Regulatory Section
Office of Diversion Control

On April 26, 2011, this section received your e-mail requesting a review of twenty-nine (29) quota applications from twenty (20) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Catalent Pharma Solutions (11427)
Vintage Pharmaceuticals (11428)
Ameridose, LLC (11429)
Penick (11430)
Mylan Chestnut Ridge Road, West Virginia (11431)
DSM (11432)
Jerome Stevens (11433)
Hospira, Inc. (11434)
Amneal - Hauppage (11435)
AMRI Rensselaer, Inc. (11436)
Sun Pharmaceuticals (11437)
Mallinckrodt St. Louis (11439)
Mallinckrodt St. Louis (11440)
Mallinckrodt St. Louis (11441)
Mallinckrodt St. Louis (11442)
Unit Dose Solutions (11443)
Unit Dose Solutions (11444)
Unit Dose Solutions (11445)
Unit Dose Solutions (11446)
Unit Dose Solutions (11447)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject: 2011 Procurement Quota Increase Request
Oxycodone (for sale)

From: Barbara J. Bockholdt, Chief
Regulatory Section
Office of Diversion Control

To: Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

On March 2, 2011, this section received your memorandum requesting a review of a quota increase submitted by [b](4) requesting a 2011 procurement quota increase from 2.0 to 9.5kg of oxycodone, an increase of 7.5kg. According to [b](4) an increase is requested for an increase in sales.

[b](4) provided year to date sales for 2011. The names of the registrants were run through NADDIS to determine if there were any ongoing field investigations. The DEA registration numbers were also run through RICS to determine if the registrations were current. Provided below are the results and recommendations.
Quota Letters Received as of May 2, 2011
(DFN: 630-08.2)

On May 3, 2011, this section received your e-mail requesting a review of forty-two (42) quota applications from thirty-one (31) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

- Fisher Clinical Services (11460)
- Noramco Delaware (11461)
- Noramco Delaware (11462)
- Noramco Delaware (11463)
- Epic Pharma (11464)
- Letco Medical (11465)
- Legacy Pharmaceutical Packaging (11466)
- Legacy Pharmaceutical Packaging (11467)
- KP Pharmaceutical Tech, Inc. (11470)
- Siegfried (11471)
- Siegfried (11472)
- Siegfried (11473)
- Agilent Technologies (11474)
- Alvogen (11475)
- Norwich (11477)
- KVK Tech, Inc. (11479)
- Sigma Aldrich (11481)
- Mylan Chestnut Ridge Road WVA (11482)
- Mylan Chestnut Ridge Road WVA (11483)
- Barr Labs (11484)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject: Quota Letters Received as of May 5, 2011 (DFN: 630-08.2)

Date: MAY 8, 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Bodckholdt, Chief
Regulatory Section
Office of Diversion Control

On May 5, 2011, this section received your e-mail requesting a review of eight (08) quota applications from manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

- Physicians Total Care (11517)
- Watson Pharmaceuticals (11518)
- Catalent Pharma Solutions (11519)
- Safecore Health, LLC (11520)
- KVK Tech, Inc. (11521)
- Mylan Pharmaceuticals (11522)
- Coating Place, Inc. (11523)
- Hisamitsu California Laboratories (11524)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or PA.
Memorandum

Subject
Quota Letters Received as of May 17, 2011 (DFN: 630-08.2)

Date
MAY 31 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On May 17, 2011, this section received your e-mail requesting a review of nine (09) quota applications with seven (07) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Alliance Contract Pharma (11531)
- Neogen Corp (11533)
- Cambrex (11534)
- Cambrex (11535)
- Amerisource Ohio (11536)
- Amerisource Ohio (11537)
- Johnson Matthey (11538)
- Paddock (11539)

QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

Currently Under Review/Investigation

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject
Quota Letters Received as of May 26, 2011
(DFN: 630-08.2)

Date

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Bogckholdt, Chief
Regulatory Section
Office of Diversion Control

On May 26, 2011, this section received your e-mail requesting a review of thirty-seven (37) quota applications from twenty-three (23) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis South-Atlantic (11552)
Amneal - Hauppage (11587)
Aurolife Pharma (11577)
Barr Laboratories (11553)
Boehringer Ingelheim (11579)
Boehringer Ingelheim (11575)
CorePharma Wood Ave (11547)
CorePharma Wood Ave (11546)
CorePharma Wood Ave (11548)
DSM (11581)
Impax Pennsylvania (11578)
Johnson Matthey (11567)
Johnson Matthey (11563)
Johnson Matthey (11565)
Johnson Matthey (11568)
Johnson Matthey (11569)
Johnson Matthey (11570)
Johnson Matthey (11564)
Johnson Matthey (11571)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

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

From
Barbara J. Bockholdt, Chief
Regulatory Section
Office of Diversion Control

On June 3, 2011, this section received your memorandum requesting a review of a quota increase submitted by [b](4) ODQ is requesting a review of [b](4) customer list, specifically, information on whether the applicant's customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

ODGR conducted NADDIS and CSA reviews of approximately ninety-seven (97) of [b](4) customers as well as on [b](4)

The following derogatory information was found on the four (4) below listed customers:

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<tr>
<th><a href="4">b</a>,<a href="7">b</a></th>
<th>Currently Under Review/Investigation</th>
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</tr>
<tr>
<td><a href="4">b</a>,<a href="7">b</a></td>
<td>Currently Under Review/Investigation</td>
</tr>
</tbody>
</table>

DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the request submitted by [b](4) for the quota increase.

If you have any questions pertaining to this information, please feel free to contact me [b](6) or SC [b](6) [b](7) [c] [b](6) [b](7) [c]
Memorandum

Subject
Quota Letters Received as of June 9, 2011 (DFN: 630-08.2)

Date
JUN 15 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Brockholdt, Chief
Regulatory Section
Office of Diversion Control

On June 9, 2011, this section received your e-mail requesting a review of twenty-six (26) quota applications from twenty-three (23) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Hisamitsu California Laboratories (11281)
Halo Pharmaceutical Company (11592)
Patheon (11593)
Noramco Delaware (11594)
Amneal - Hauppage (115965)
Alza Vacaville (11597)
Novel Laboratories (11598)
Cerilliant (11600)
Watson (11602)
B&B Pharmaceuticals (11604)
Kremers Urban Pharma (11605)
Watson Pharma (11607)
Elan Holdings (11608)
Almac Clinical Services (11610)
Alza Vacaville (11611)
Alza Vacaville (11612)
Siegfried (11613)
Mallinckrodt St. Louis (11614)
Catalent Pharma Solutions (11615)
Halo Pharmaceutical Company (11616)
QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

Currently Under Review/Investigation

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of June 23, 2011
(DFN: 630-08.2)

Date
JUL 01 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On June 23, 2011, this section received your e-mail requesting a review of nineteen (19) quota applications from eighteen (18) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Johnson Matthey (11456)
- Watson Pharma (11603)
- Norac (11622)
- Banner California (11623)
- Hisamitsu California Laboratories (11624)
- Alza Vacaville (11625)
- Alza Vacaville (11626)
- Catalent Pharma Solutions (11627)
- Mirror Pharmaceuticals (11628)
- Bilcare Global Clinical Supplies (11630)
- Pharmaceutical Associates (11631)
- Endo Pharmaceuticals (11634)
- Mallinckrodt St. Louis (11637)
- VistaPharm (11638)
- Alvogen (11639)
- Novartis Consumer Health Lincoln (11640)
- Hospira, Inc. NC (11646)
- Mikart Marietta Boulevard (11647)
- Mikart Marietta Boulevard (11647) 2 of 2
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of July 1, 2011
(DFN. 630-08.2)

Date
JUL 12 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diverion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On July 01, 2011, this section received your e-mail requesting a review of twelve (12) quota applications from seven (07) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Freedom Pharma (11651)
Freedom Pharma (11652)
Freedom Pharma (11653)
Freedom Pharma (11654)
Freedom Pharma (11655)
Med Shop Total Care (11656)
Mylan Pharmaceuticals (11657)
Mylan Pharmaceuticals (11658)
Pharmaceutical Manufacturing (11659)
Epic Pharma (11660)
Watson Connecticut (11661)
Halo Pharmaceutical Company (11678)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.

Vol. II Page 381
Subject: 2011 Procurement Quota Increase Request
Hydrocodone
(DFN:630-08.2)

Date: JUL 1’2 2011

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

From
Barbara J. Boeckholdt, Chief
Regulatory Section
Office of Diversion Control

On April 26, 2011, this section received your memorandum requesting a review of a quota increase submitted by (b)(4) is requesting a 2011 procurement quota increase of 4,913kg of hydrocodone. You indicate that, if granted, the total 2011 procurement quota would be 17,713kg of hydrocodone. ODQ is requesting a review of (b)(4) customer list, specifically, information on whether the applicant’s customers are currently under investigation or are subject of an order to show cause or immediate suspension order. The original request was returned to ODQ due to the lack of (b)(4) customers’ DEA registration numbers. On May 13, 2011, ODQ resubmitted the memorandum submitted on April 26, 2011 with the appropriate information.

ODGR conducted NADDIS and CSA reviews of approximately one hundred forty-two (142) of (b)(4) customers as well as on (b)(4)

The following derogatory information was found on the eight (8) below listed customers:

Currently Under Review/Investigation
Currently Under Suspension
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Order to Show Cause
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation

Because of the pending investigations of the above listed customers, ODG recommends that ODQ adjust the quota allotted to (b)(4) accordingly.

If you have any questions pertaining to this information, please feel free to contact me (b)(6); (b)(7)(C) or SC

Vol. II Page 382
Memorandum

Subject
Quota Letters Received as of July 14, 2011
(DFN: 630-08.2)

Date
JUL 2 1 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diverison Control

From
Barbara J. Boeckholdt
Barbara J. Boeckholdt, Chief
Regulatory Section
Office of Diversion Control

On July 14, 2011, this section received your e-mail requesting a review of thirty (30) quota applications from twenty-seven (27) registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODF 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Anesta (11676)
Teva Pharmaceuticals (11677)
AAI Pharma 1726 N. 23rd St (11679)
Vintage Pharmaceuticals (11680)
Vintage Pharmaceuticals (11681)
Catalent Pharma Solutions (11683)
Norwich Pharmaceuticals (11684)
B & B (11685)
Fisher - Bristol, PA (11686)
Clinical Supplies Mgmt (11687)
Barr New Jersey (11688)
Janssen Puerto Rico (11689)
Core Rx (11690)
Durect (11692)
FormuRx (11693)
Elite (11694)
Hospira, Inc. NC (11698)
Watson Connecticut (11699)
Cerilliant (11700)
CorePharma Wood Ave (11701)
<table>
<thead>
<tr>
<th>Company Name</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patheon</td>
<td>11702</td>
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<tr>
<td>King Pharmaceuticals</td>
<td>11703</td>
</tr>
<tr>
<td>Impax Pennsylvania</td>
<td>11704</td>
</tr>
<tr>
<td>CAPS</td>
<td>11705</td>
</tr>
<tr>
<td>Watson Connecticut</td>
<td>11707</td>
</tr>
<tr>
<td>UCB Manufacturing (former Celltech NY)</td>
<td>11708</td>
</tr>
<tr>
<td>UCB Manufacturing (former Celltech NY)</td>
<td>11709</td>
</tr>
<tr>
<td>Dispensing Solutions, Inc.</td>
<td>11712</td>
</tr>
<tr>
<td>Novartis Consumer Health Lincoln</td>
<td>11713</td>
</tr>
</tbody>
</table>

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me.
Memorandum

Subject: Quota Letters Received as of July 19, 2011
(DFN: 630-08.2)

Date: JUL 21 2011

From: Barbara Boekholdt, Chief
Regulatory Section
Office of Diversion Control

To: Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

On July 19, 2011, this section received your e-mail requesting a review of sixteen (16) quota applications from registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Medisca (11559)
Upsher-Smith (11714)
Upsher-Smith (11715)
Par (11716-1)
Par (11716-2)
Patheon (11717)
Purdue (11718)
DPT Paco Way (11719)
Tris Pharma, Inc. (11720)
UMISS (11721)
Aurolife Pharma (11722)
Impax Pennsylvania (11723)
Sandoz (11724)
Lannett (11725)
Halo Pharmaceutical Company (11726)
Epic Pharma (11727)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of July 22, 2011
(DFN: 630-08.2)

Date
JUL 29 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Bockholdt, Chief
Regulatory Section
Office of Diversion Control

On July 22, 2011, this section received your e-mail requesting a review of twenty-six (26) quota applications from twenty-three (23) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Med-Pharmex (11200)
Fisher Clinical Services (11728)
Interchem Corp (11729)
Restek (11730)
PD-RX Pharmaceuticals (11731)
Catalent Pharma Solutions (11732)
Amneal – Hauppage (11733)
Tris Pharma, Inc. (11734)
Hisamitsu California Laboratories (11735)
Epic Pharma (11736)
Aptuit, Inc. (11737)
Par Pharmaceuticals (11738)
Siegfried (11739)
Siegfried (11740)
PD-RX Pharmaceuticals (11743)
AmeriSource Ohio (11744)
Nostrum Labs, Inc. (11745)
Aptuit, Inc. (11746)
UPM Pharmaceuticals (11747)
Watson Pharmaceuticals (11748)
Metrics (11749)
Janssen Puerto Rico (11750)
Elan Holdings (11752)
Aurolife Pharma (11753)
Pisgah Labs (11754)
Great Southern (11755)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of July 29, 2011
(DFN: 630-08.2)

Date
AUG 03 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On July 29, 2011, this section received your e-mail requesting a review of twenty (20) quota applications from fifteen (15) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Patheon (11757)
- Johnson Matthey (11758)
- Johnson Matthey (11759)
- Johnson Matthey (11760)
- Johnson Matthey (11761)
- University of Mississippi (11762)
- ANI Pharmaceuticals, Inc. (11763)
- Cerilliant (11764)
- Chemtos (11765)
- Penick (11766) (1 of 2)
- Penick (11766) (2 of 2)
- Letco Medical (11766)
- Noramco Georgia (11769)
- Norac (11770)
- Watson Pharmaceuticals (11771)
- HiTech (11772)
- Penick (11773) (1 of 2)
- Penick (11773) (2 of 2)
- Metrics (11774)
- AustarPharma (11775)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of August 4, 2011
(DFN: 630-08.2)

Date
AUG 09 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On August 4, 2011, this section received your e-mail requesting a review of fifteen (15) quota applications from fifteen (15) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Archimica (11777)
Tris Pharma, Inc. (11778)
Anderson Packaging, Inc. (11779)
Paddock (11781)
Noramco (11781)
Fleming and Co. (11785)
Watson Pharmaceuticals (11786)
Mallinckrodt St. Louis (11787)
Cambrex (11788)
Microgenics (11789)
Amneal - Hauppage (11790)
Fisher Clinical (11791)
Catalent Pharma Solutions (11792)
Hospira, Inc. NC (11793)
DSM (11794)

QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

Under Investigation/Discussion Ongoing
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or PA.
Memorandum

Subject

2011 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

Date

AUG 11 2011

To

Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section (ODQ)
Office of Diversion Control

From

Barbara J. Bogeckholdt, Chief
Regulatory Section (ODQ)
Office of Diversion Control

On August 4, 2011, this section received your memorandum requesting a review of a quota increase submitted by ODQ is requesting a review of customer list, specifically, information on whether the applicant's customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

ODGR conducted NADDIS and CSA reviews of approximately one hundred and seventy-nine (179) of customers as well as on

The following information was found on and the below listed customers:

Currently Under Review/Investigation
Retired
Retired
Retired
Currently Under Suspension
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
Currently Under Review/Investigation
DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the request submitted by [b](4) for the quota increase.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of August 15, 2011.
(DFN: 630-08.2)

Date
AUG 22 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From: Barbara J. Bogekholdt, Chief
Regulatory Section
Office of Diversion Control

On August 17, 2011, this section received your e-mail requesting a review of seventeen (17) quota applications from 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis Elizabeth LLC (109037)
Alza Corporation (109028)
Ameridose, LLC (109030)
Ameridose, LLC (109063)
Amneal Pharmaceuticals of NY, LLC (109141)
Cody Laboratories, Inc. (109075)
Hospira Inc (109099)
Janssen Cilag Manufacturing LLC (109098)
Mallinckrodt Inc (109119)
Mallinckrodt LLC (109072)
Micron Technologies (109060)
Neos Therapeutics, LP (109033)
Noramco (109130)
Ohm Laboratories (109034)
Purdue Pharmaceuticals LP (109086)
Sharp Corporation (109031)
West-Ward Pharmaceuticals Corp (109113)

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of August 17, 2011
(DFN: 630-08.2)

Date
AUG 22 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Blockhoeldt, Chief
Regulatory Section
Office of Diversion Control

On August 17, 2011, this section received your e-mail requesting a review of twenty-one (21) quota applications from eighteen (18) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

AmeriSource Ohio (11795)
ECI Pharmaceuticals (11796)
Tris Pharma, Inc (11797)
Noramco (11798)
Watson Pharmaceuticals (11799)
Watson Pharmaceuticals (11800)
Watson Pharmaceuticals (11801)
DSM (11802)
Safecor Health, LLC (Regional Service Center (11803)
Nexgen Pharma, Inc (11804)
Cerilliant (11805)
PD-RX Pharmaceuticals (11807)
Advanced Pharma (11808)
Advanced Pharma (11809)
OHM Labs (11810)
Elan Holdings (11811)
Cambrex (11814)
Cambrex (11815)
Bio Pharm (11816)
Norac (11770)
QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC (b)(6);(b)(7)(C) (C).
Memorandum

Subject
Quota Letters Received as of August 22, 2011
(DFN: 630-08.2)

Date
SEP 06 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Booskholdt, Chief
Regulatory Section
Office of Diversion Control

On August 22, 2011, this section received your e-mail requesting a review of five (05) quota applications of registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis South-Atlantic (11819)
Mylan Chestnut Ridge Road, W.VA (11820)
PCCA (11821)
Chemtos (11822)
Lehigh Valley Technologies, Inc (11823)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of August 26, 2011
(DFN: 630-08.2)

Date
SEP 06 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Blockholdt, Chief
Regulatory Section
Office of Diversion Control

On August 26, 2011, this section received your e-mail requesting a review of eight (08) quota applications of registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Hercon Labs Corp (11824)
- Johnson Matthey (11825)
- Aphenix Pharma (11826)
- Rhodes (11827)
- Hisamitsu California Laboratories (11828)
- Tris Pharma, Inc. (11830)
- Lehigh Valley Technologies, Inc. (11831)
- AmeriSource Ohio (11832)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.

Vol. II Page 400
Memorandum

Subject
Quota Letters Received as of September 2, 2011
(DFN: 630-08.2)

Date
SEP 08 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On September 6, 2011, this section received your e-mail requesting a review of eighteen (18) quota applications from sixteen (16) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

PD-RX Pharma, Inc. (11833)
Norac (11834)
Johnson Matthey (11835)
Johnson Matthey (11836)
Sandoz (11837)
Patheon (11838)
Metrics (11840)
Metrics (11841)
Vintage Pharmaceuticals (11843)
Vintage Pharmaceuticals (11844)
AMRI Rensselaer, Inc. (11845)
PharmaForm (11846)
ANI Pharmaceuticals, Inc. (11847)
Johnson Matthey (11848)
Cerilliant (11849)
Watson Pharma (11850)
Pharmaceutics International (11851)
Elan Holdings (11852)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject: 2011 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

Date: SEP 08 2011

To: Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section (ODQ)
Office of Diversion Control

From: Barbara J. Boeckholdt, Chief
Regulatory Section (ODG)
Office of Diversion Control

On August 4, 2011, this section received your memorandum requesting a review of a quota increase submitted by [redacted]. ODQ is requesting a review of [redacted] customer list, specifically, information on whether the applicant's customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

ODG conducted NADDIS and CSA reviews of approximately one hundred and seventy-nine (179) of [redacted] customers as well as an in-depth investigation of [redacted]. ODG has determined that [redacted] request for a quota increase should be denied. Grounds for this action are based upon [redacted] failure to provide effective control against diversion of the controlled substances they manufacture as required by Title 21 USC 824(a)(4).

If you have any questions pertaining to this information, please feel free to contact me [redacted] or SC [redacted].
On September 20, 2011, this section received your memorandum requesting a review of Freedom Pharmaceuticals' customers' list, specifically, 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.

Freedom Pharmaceuticals provided a list of its customers. The names of the customers were run through NADDIS to determine if there were any open field investigations. The DEA registration numbers were also run through RICS to determine if the registrations were current. These checks yielded the following results:

No derogatory information was found

DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the request submitted by Freedom Pharmaceuticals for the quota increase.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
2011 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)

Date
OCT 04 2011.

To
Christine A. Sanncrud, Ph.D., Chief Drug & Chemical Evaluation Section (ODQ) Office of Diversion Control

From
Barbara J. Booschholdt, Chief Regulatory Section (ODG) Office of Diversion Control

On August 19, 2011, this section received your memorandum requesting a review of a quota increase submitted by (b)(4). ODQ is requesting a review of (b)(4) customer list, specifically, information on whether the applicant's customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

ODGR conducted NADDIS and CSA reviews of approximately one hundred and fifty-five (155) of (b)(4) customers as well as an in-depth investigation of (b)(4).

The below listed information was found on (b)(4) customers:

Currently Under Review/Investigation

Currently Under Review/Investigation

Currently Under Review/Investigation

Currently Under Review/Investigation

Currently Under Review/Investigation
Based upon a review of customers, ODG recommends that ODQ adjust the quota granted to this company. Two of customers are currently under an Immediate Suspension Order and nine (9) customers are under Review/Investigation.

Quota should be reduced by at least the total kilogram amounts sold by the company to the above listed customers.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of September 19, 2011
(DFN: 630-08.2)

Date
OCT 05 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Bjorkholdt, Chief
Regulatory Section
Office of Diversion Control

On September 19, 2011, this section received your e-mail requesting a review of eleven (11) quota applications from ten (10) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

Clinical Supplies Management (11853)
Mikart (11854)
Almac Clinical Services, Inc (11855)
Vista Pharm Inc (11856)
Medisca Inc. (11857)
Johnson Matthey (11858)
Vortech Pharmaceuticals Ltd (11859)
Cerilliant Corporation (11860)
Paddock Laboratories, LLC (11862)
Vintage Pharmaceuticals (11843)
Vintage Pharmaceuticals (11844)

Per consultation with the field offices, Drug, Theft, and Loss queried, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or PA.

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Memorandum

Subject
Quota Letters Received as of September 26, 2011
(DFN: 630-08.2)

Date
OCT 05 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diverisoti Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On September 26, 2011, this section received your e-mail requesting a review of thirty-four (34) quota applications from thirty-three (33) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis MidAtlantic LLC (109528)
Amneal Pharma of New York LLC (109260)
Archimica, Inc (109471)
B&B Pharmaceuticals (109489)
Bio-Pharm Inc (109258)
Boehringer Ingelheim Chem Inc (109259)
Capricorn Pharma Inc (109463)
Cerilliant Corporation (109501)
CorePharma, LLC (109517)
DSM Pharmaceuticals, Inc. (109488)
Epic Pharma LLC (109493)
Glatt Air Techniques Inc. (109472)
Mallinckrodt Inc (109487)
Mylan Pharmaceuticals Inc (109366)
Mylan Pharmaceuticals Inc (109420)
Mylan Pharmaceuticals Inc (109263)
Neos Therapeutics, LP (109184)
Noramco Inc (109523)
Noramco Inc (109524)
Norwich Pharmaceuticals Inc (109462)
Noven Pharmaceuticals, Inc (109499)
Patheon Pharmaceuticals, Inc (109500)
Purdue Pharmaceuticals LP (109195)
Sharp Corporation (109264)
Specialty Compounding LLC (109465)
Stat RX USA LLC (109521)
Tris Pharma Inc (109520)
Vista Pharm Inc (109490)
Watson Laboratories Inc – Florida (109503)
Watson Laboratories Inc – Florida (109505)
Emerson Resources, Inc (11865)
Thermofisher Scientific (11866)
Nesher Pharmaceuticals LLC (11868-1)
Nesher Pharmaceuticals LLC (11868-2)

Please note that currently under investigation, listed above is not the Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
On September 30, 2011, this section received your memorandum requesting a review of Mikart Inc’s customers list, specifically, 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.

Mikart Inc. provided a list of [b](4) customers. The names of the customers were run through NADDIS to determine if there were any open field investigations. The DEA registration numbers were also run through RICS to determine if the registrations were current. These checks yielded the following results:

No derogatory information was found

DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the request submitted by Freedom Pharmaceuticals for the quota increase.

If you have any questions pertaining to this information, please feel free to contact me [b](6) or SC
Memorandum

Subject: 2011 Procurement Quota Increase Request
Hydrocodone (DFN: 630-08.2)

Date: OCT 13 2011

To: Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section (ODQ)
Office of Diversion Control

From: Barbara J. Boesholdt, Chief
Regulatory Section (ODG)
Office of Diversion Control

On September 30, 2011, this section received your memorandum requesting a review of a quota increase submitted by (b)(4) [DeA (b)(4);(b)(7)(E)] specifically, information on whether the applicant’s customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

ODGR conducted NADDIS and CSA reviews of approximately one hundred and thirty-six (136) of (b)(4) [DeA (b)(4);(b)(7)(E)] customers as well as an in-depth investigation of (b)(4) [DeA (b)(4);(b)(7)(E)]

The below listed information was found on (b)(4) [DeA (b)(4);(b)(7)(E)] customers:

- **Currently Under Review/Investigation**
  (b)(4);(b)(7)(E)

- **Currently Under Review/Investigation**
  (b)(4);(b)(7)(E)

- **Currently Under Suspension**
  (b)(4);(b)(7)(E)

- **Currently Under Review/Investigation**
  (b)(4);(b)(7)(E)

- **Currently Under Review/Investigation**
  (b)(4);(b)(7)(E)

- **Currently Under Review/Investigation**
  (b)(4);(b)(5);(b)(7)(E)

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Based upon a review of (b)(4) customers, ODG recommends that ODQ adjust the quota granted to this company. One of (b)(4) customer is currently under an Immediate Suspension Order (b)(4); twelve (12) customers are under Review/Investigation; and three (3) are retired.

Quota to (b)(4) should be reduced by at least the total kilogram amounts sold by the company to the above listed customers.
If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of October 14, 2011 (DFN: 630-08.2)

Date
OCT 20 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On October 14, 2011, this section received your e-mail requesting a review of five (5) quota applications of four (4) registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Diamond Animal Health (11880)
Sun Pharmaceutical (11882)
Johnson Matthey (11885)
Johnson Matthey (11886)

Per consultation with the DEA Atlanta Field Division, further investigation/review is needed for the quota request of (b)(4) due to a name change.

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me (b)(6) or PA (b)(6).
October 10, 2011

Dr. Christine Sannerud, Ph.D.
Drug Enforcement Administration
Office of Diversion Control
8701 Morrissette Drive
Alexandria, Virginia 22301

RE: Additional Procurement Quota for Methylphenidate HCl
Registration Number [b](4)[d](7)[E]

Dr. Sannerud:

This letter is to request additional procurement quota of [b](4) of (DEA code 1724) Methylphenidate HCl anhydrous base.

We are providing the following data as support for the additional quota request.

<table>
<thead>
<tr>
<th>Base (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="4">b</a></td>
</tr>
</tbody>
</table>

We also request that your office consider a pending return of [b](4) kg. If considered, our total quota request is:

Feel free to contact me at [b](6) with any questions you have concerning this request.

Sincerely,

Director, Materials Management
From: [REDACTED]
Sent: Tuesday, October 18, 2011 5:29 PM
To: [REDACTED]
Subject: [REDACTED] (Letters Received as of October 14, 2011)

This company is changing ownership, have not seen anything requesting the change of name/ownership yet. Did they indicate anything in their request? However, they are on our work plan FY 12 and the DI is aware of the anticipated change of name and ownership. Let me know if I can do anything else.

Group Supervisor
DEA Atlanta Division

"In any moment of decision the best thing you can do is the right thing, and the next thing is the wrong thing, and the worst thing that you can do is nothing."
Theodore Roosevelt

From: [REDACTED]
Sent: Tuesday, October 18, 2011 4:15 PM
To: [REDACTED]
CC: [REDACTED]
Subject: Quota Request (Letters Received as of October 14, 2011)
Importance: High

Hello [REDACTED]

The request I sent for [REDACTED] has another name, have they requested a name change, or is this change of ownership (reason for name change)? RICS do not reflect the new name, SEE BELOW.
According to the documentation received from each company the names are correct:

- (b)(6)
- (b)(7)

CSA has yet to be updated with the current information.

Thanks,

Program Analyst
Quota Unit (ODQ)
UN Reporting and Quota Section
Office of Diversion Control
Drug Enforcement Administration

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

Can you please verify the registrants name, based on RICS the NAME below do not match the DEA number in RICS.
Good Afternoon,

Below is a list of quota applications from DEA-registered manufacturers received as of October 14, 2011.

We request that ODG and ODP review for pending administrative/legal action against these applicants and advise ODQ of your findings.

Thank you in advance.

<table>
<thead>
<tr>
<th>Log In #</th>
<th>Company Name</th>
<th>Registration #</th>
</tr>
</thead>
<tbody>
<tr>
<td>11880</td>
<td></td>
<td>(b)(4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)(7)(E)</td>
</tr>
</tbody>
</table>
Program Analyst
Quota Unit (XDQ)
UN Reporting and Quota Section
Office of Diversion Control
Drug Enforcement Administration
On October 7, 2011, this section received your e-mail requesting a review of thirty-eight (38) quota applications from twenty-six (26) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION**

- Actavis Elizabeth LLC (109554)
- Actavis Southatlantic LLC (109591)
- Akorn, Inc. (109553)
- Akorn, Inc. (109552)
- Cerilliant Corporation (109590)
- Corepharma, LLC (109545)
- Corepharma, LLC (109546)
- DPT Lakewood, LLC (109547)
- Halo Pharmaceutical, Inc (109588)
- Halo Pharmaceutical, Inc (11878)
- Hisamitsu California Laboratories (11879)
- Hospira, Inc. (109595)
- Johnson Matthey, Inc. (109558)
- Johnson Matthey, Inc. (11876)
- KVK Tech, Inc. (11870)
- KVK Tech, Inc. (11872)
- KVK Tech, Inc. (11873)
- KVK Tech, Inc. (11874)
- KVK Tech, Inc. (11875)
Per consultation with the field office, ODGR received an email from GS Angeles Field Division requesting the cancellation of quota from Med-Pharmex, Inc. #11871 (DEA). ODGR received this request via an email from Med-Pharmex, Inc. Based on this information, ODG suggests that you cancel the quota for Phenylpropanolamine (PPA).

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or PA.
FW: PPA Quota for Med-Pharmex, Inc.

FYI

From: [redacted]
Sent: Monday, October 24, 2011 9:38 AM
To: [redacted]
Subject: FW: PPA Quota for Med-Pharmex, Inc.

I will get Mr. [redacted] to cancel his request for the addition of drug code for PPA via letter/fax.

Please tell the HQS quota lady [redacted] She had contacted you last week about Med-Phm and the setting of her annual allotments. I have never been in direct contact with her.

From: [redacted]
Sent: Saturday, October 22, 2011 12:26 PM
To: [redacted]
Subject: PPA Quota for Med-Pharmex, Inc.

So, please cancel our request for a quota for this year.

Thank you

Regards

Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

Phone: [redacted]
Fax: [redacted]
Memorandum

Subject
Quota Letters Received as of October 17, 2011 (DFN: 630-08.2)

Date
NOV 04 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diverison Control

From
Barbara J. Bobckholdt, Chief
Regulatory Section
Office of Diverison Control

On October 17, 2011, this section received your e-mail requesting a review of thirty-eight (38) quota applications from nineteen (19) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Prof Compounding Ctrs. of America (109596)
Prof Compounding Ctrs. of America (109598)
Corepharma, LLC (109601)
Vista Pharm, Inc. (109602)
Actavis Southatlantic LLC (109591)
KVK Tech, Inc. (109614)
KVK Tech, Inc. (109615)
KVK Tech, Inc. (109615)
KVK Tech, Inc. (109616)
KVK Tech, Inc. (109617)
Mallinckrodt, Inc. (109618)
Almac Clinical Services, Inc. (109671)
Siegfried (USA) (109683)
Siegfried (USA) (109684)
Siegfried (USA) (109686)
KVK Tech, Inc. (109688)
Catalent Pharma Solutions, Inc. (109690)
Anderson Packaging, Inc. (109692)
Almac Clinical Services, Inc. (109708)
Johnson Matthey, Inc. (109716)
Per consultation with the field office, ODGR received an email from GS (F) of the Los Angeles Field Division requesting the cancellation of quota from Med-Pharmex, Inc. #109620 (DEA (b)(4);(b)(7)(E)). LAFD) received this request via an email from one of Med-Pharmex, Inc. Based on this information, ODG suggests that you cancel the quota for Phenylpropanolamine (PPA).

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications, with the exception of Med-Pharmex, Inc (109620).

If you have any questions pertaining to this information, please feel free to contact me or PA.
Memorandum

Subject
Quota Letters Received as of November 1, 2011
(DFN: 630-08.2)

Date
NOV 04 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On November 1, 2011, this section received your e-mail requesting a review of two lists of forty-five (45) quota applications from twenty-six (26) 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Halo Pharmaceutical Inc. (109760)
- Prof Compounding Centers of (109761)
- Mallinckrodt LLC (109762)
- Prof Compounding Centers of (109763)
- Nesher Pharmaceuticals USA LLC (109774)
- Noramco Inc. (109775)
- Nesher Pharmaceuticals USA LLC (109777)
- Watson Laboratories Inc. (109778)
- West-Ward Pharmaceuticals Corp (109779)
- Nesher Pharmaceuticals USA LLC (109780)
- Nesher Pharmaceuticals USA LLC (109781)
- Catalent Pharma Solutions, Inc. (109782)
- Catalent Pharma Solutions, Inc. (109783)
- Nesher Pharmaceuticals USA LLC (109784)
- Nesher Pharmaceuticals USA LLC (109786)
- Nesher Pharmaceuticals USA LLC (109787)
- Mallinckrodt LLC (109788)
- Paddock Laboratories LLC (109798)
- Paddock Laboratories LLC (109799)
- Paddock Laboratories LLC (109801)
- Paddock Laboratories LLC (109802)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

**QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION**

Paddock Laboratories LLC (109803)
Johnson Matthey Inc. (109804)
Johnson Matthey Inc. (109805)
Johnson Matthey Inc. (109806)
Akorn, Inc. (109812)
Akorn, Inc. (109815)
Noramco Inc. (109816)
Catalent Pharma Solutions, Inc. (109823)
Vista Pharm Inc. (109830)
Elan Holdings Inc. (109831)
Elan Holdings Inc. (109835)
Paddock Laboratories Inc. (109845)
Paddock Laboratories Inc. (109846)
Vista Pharm Inc. (109846)
Alltech Associates Inc. (109863)
Cambrex Charles City (109875)
Generic Pharmaceutical Svc In (109880)
Great Southern Laboratories (109891)
Cambrex Charles City (109911)
ODG is recommending that ODQ deny the quota increase for \[ (b)(4) \] based upon the above stated information.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
Quota Letters Received as of October 17, 2011
(DFN: 630-08.2)

Date

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

Reference is made to your October 17, 2011 e-mail requesting a review of thirty-eight (38) quota applications from nineteen (19) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

One of the above stated requests was from Med-Pharmex, Inc. #109620, DEA (b)(4)(b)(7)(E) Med-Pharmex, in its letter, requested an increase for Phenylpropanolamine (PPA) and Pentobarbital but later requested their request for Phenylpropanolamine be withdrawn. ODGR did not address the request for Pentobarbital. On November 9, 2011, SC (b)(6)(b)(7)(C) contacted the Los Angeles Field Division as well as conducted checks in the various databases. No derogatory information was found.

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from this registrant. Based on this information, ODG suggests that you proceed with the completion of the quota application for Med-Pharmex, Inc.

If you have any questions pertaining to this information, please feel free to contact me (b)(6)(b)(7)(C) or SC (b)(6)(b)(7)(C).

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Memorandum

Subject
Quota Letters Received as of November 8, 2011 (DFN: 630-08.2)

Date
NOV 10 2011

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On November 8, 2011, this section received your e-mail requesting a review of eight (8) quota applications of registered manufacturers to determine if there were 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Anesta (11887)
- KP Pharmaceutical (11888)
- Metrics (11889)
- King Pharmaceuticals (11890)
- DSM Pharmaceuticals (11891)
- Vintage Pharmaceuticals (11892)
- Mylan Chestnut Ridge Road, WV (11893) (1 of 2)
- Mylan Pharmaceuticals (11893) (2 of 2)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Quota Letters Received as of November 15, 2011
(DFN: 630-08.2)

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On November 15, 2011, this section received your e-mail requesting a review of eighteen (18) quota applications of fourteen (14) registered manufactures to determine if there were any pending administrative/legal actions against these applicants 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 APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- King Pharmaceuticals (11895)
- Patheon Pharmaceuticals Inc (109923)
- Mallinckrodt LLC (109925)
- DSM Pharmaceuticals, Inc (109929)
- Watson Laboratories Inc-Florida (109935)
- LNK International Inc (109936)
- EON Labs, Inc. (109945)
- EON Labs, Inc. (109949)
- US Compounding, Inc (109951)
- EON Labs, Inc. (109952)
- Metrics (109963)
- Chemtose, LLC (109967)
- EON Labs, Inc. (109974)
- EON Labs, Inc. (109980)
- AAIPharma Services Corp (109981)
- Patheon Pharmaceuticals Inc (109999)
- AKORN, Inc (110028)
- AKORN, Inc (110029)
Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject
2011 Procurement Quota Increase Request
Oxycodone (For Sale)
(DFN: 630-08.2)

Date

To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section (ODQ)
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section (ODG)
Office of Diversion Control

On November 10, 2011, this section received your memorandum requesting a review of a quota increase submitted by ODQ. ODQ is requesting a review of customers specifically, information on whether the applicant's customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

Provided a list of nine (9) customers. The names of the customers were run through NADDIS to determine if there were any open field investigations. The DEA registration numbers were also run through RICS to determine if the registrations were current. These checks found that eight (8) of the customers had no derogatory information.

DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the request submitted for the quota increase.

The below listed customer was found to have derogatory information against its registration:

Currently Under Review/Investigation

Based upon a review of this customer, ODG recommends that ODQ adjust the quota granted to this registrant.

If you have any questions pertaining to this information, please feel free to contact me or SC

Vol. II Page 432
On November 17, 2011, this section received your memorandum requesting a review of a quota increase submitted by [redacted]. ODQ is requesting a review of [redacted] customer list, specifically, information on whether the applicant's customers are currently under investigation or are subject of an order to show cause or immediate suspension order.

ODGR conducted NADDIS and CSA reviews of approximately one hundred and thirty-two (132) of [redacted] customers as well as an in-depth investigation of [redacted]

The below listed information was found on [redacted] customers:

- Currently Under Review/Investigation
  - (b)(4);(b)(7)(E)
- Currently Under Review/Investigation
  - (b)(4);(b)(7)(E)
- Currently Under Review/Investigation
  - (b)(4);(b)(7)(E)
- Currently Under Review/Investigation
  - (b)(4);(b)(7)(E)
Based upon a review of customers, ODG recommends that ODQ adjust the quota granted to this company. One of the customers is currently under an Immediate Suspension Order; twelve (12) customers are under Review/Investigation; and three (3) are retired.

Quota to should be reduced by at least the total kilogram amounts sold by the company to the above listed customers.

If you have any questions pertaining to this information, please feel free to contact me or SC.
Memorandum

Subject: 2012 Initial Quota Requests by Registration Number (DFN: 630-08.2)

Date: DEC 13 2011

To: Christine A. Sannerud, Ph.D., Chief
    Drug & Chemical Evaluation Section
    Office of Diversion Control

From: Barbara J. Boonkholdt, Chief
      Regulatory Section
      Office of Diversion Control

On December 2, 2011, this section received your e-mail requesting a review of one hundred ninety-seven (197) initial quota requests from registered manufacturers to determine if there were 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.

Of the one hundred and ninety-seven requests reviewed, there were only five registrants with adverse or derogatory information against their registrations.

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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Vol. II Page 436
Quotas should be reduced by at least the total kilogram amounts sold by the company to the above listed customers.

If you have any questions pertaining to this information, please feel free to contact me or SC.