

# Memorandum



1/4/11  
(b)(6);(b)(7)(C)

Subject Quota Letters Received as of December 20, 2010 (DFN: 630-08.2)	Date  JAN 04 2011
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To  
Christine A. Sannerud, Ph.D., Chief  
Drug & Chemical Evaluation Section  
Office of Diversion Control

From  
*Barbara J. Boockholdt*  
Barbara J. Boockholdt, 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) (b)(4);(b)(7)(E)

### QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

(b)(4);(b)(7)(E) 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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

# Memorandum



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

Subject Quota Letters Received as of January 06, 2011 (DFN: 630-08.2)	Date  JAN 13 2011
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To  
Christine A. Sannerud, Ph.D., Chief  
Drug & Chemical Evaluation Section  
Office of Diversion Control

From  
*Barbara J. Boockholdt*  
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)

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

Mallinckdrodt St. Louis (10975)  
 Cambrex (10976)  
 Anesta LLC (10978)  
 Sigma-Aldrich Research Biochemicals (10979)  
 Mylan Chestnut Ridge Road West VA (10939)  
 Halo Pharmaceutical Company (10941)  
 Amneal – Hauppauge (10942)  
 Watson (10943)  
 Watson Connecticut (10944)  
 Elite Labs (10957)  
 Elite Labs (10958)  
 AmeriSource Ohio (10959)  
 AA1 Pharma (10960)  
 Bryant Ranch Prepack (10961)  
 Fisher Clinical (10962)  
 Penick Corp (10963)  
 Dispensing Solutions, Inc. (10964)  
 Rhodes Technologies (10980)  
 Watson Labs (10981) (2 of 2)  
 Watson Labs (10981) (1 of 2)  
 Elite (10982)  
 Sigma-Aldrich Research Biochemicals (10983)  
 Cody Labs (10984)  
 Vintage Pharmaceuticals (10925)  
 Watson (10931)  
 Watson (10932)  
 Catalent Pharma Solutions (10934)  
 Eurand (10935)  
 AMRI Rensselear, Inc (10937)  
 KVK Tech, Inc. (10938)  
 Southwest Research Institute (10917)  
 Amneal Pharmaceuticals (10919)  
 AMRI Rensselear, Inc. (10921)  
 Vintage Pharmaceuticals (10922)  
 Vintage Pharmaceuticals (10923)  
 Vintage Pharmaceuticals (10923) 10924

(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 (b)(6);(b)(7)(C) or SC

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

# Memorandum



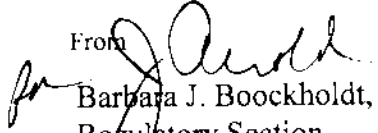
(b)(6);(b)(7)(C)

Subject Quota Letters Received as of January 13, 2011 (DFN: 630-08.2)	Date  JAN 18 2011
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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)

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

Fisher Clinical (11010)  
APP Pharmaceuticals (11011)  
Baxter (11014)

(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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

# Memorandum



1/26/11  
(b)(6);(b)(7)(C)

Subject

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

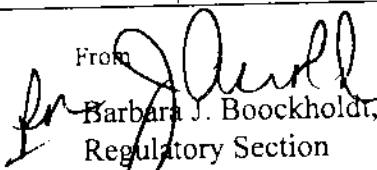
Date

JAN 21 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)

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

## QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

# Memorandum



1/25/11  
(b)(6);(b)(7)(C)

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

*James A. ...*  
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)

(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 (b)(6);(b)(7)(C) or SC

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



# Memorandum



Subject:

Additional Quota Requests as of January 25, 2010  
(DIN: 630-08.2)

Date:

JAN 27 2010

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 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 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

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

(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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

# Memorandum



1/27/11  
(b)(6);(b)(7)(C)

Subject

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

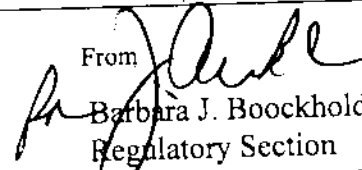
Date

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.

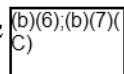
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

## QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

(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.



# Memorandum



2/2/11

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

Subject Quota Letters Received as of January 31, 2011 (DFN: 630-08.2)	Date  FEB 02 2011
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To

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

From *James A. Boockholdt*  
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.

## QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Fleming & Co (11069)
- King Pharmaceutical (11070)
- Metrics (11071)
- Watson (11072)
- Watson (11072)(2 of 2)
- Amneal Pharmaceuticals (11073)
- Glatt Air (11074)
- Metrics (11075)
- Fisher Clinical Services (11076)(1 of 3)
- Fisher Clinical Services (11076)(2 of 3)
- Fisher Clinical Services (11076)(3 of 3)
- TG United (11077)
- Ameridose, LLC (11078) (1 of 2)
- Ameridose, LLC (11078) (2 of 2)
- Bilcare (11079)
- Mallinckrodt St. Louis (11080)

(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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)



# Memorandum

Subject (b)(4);(b)(7)(E) 2011 Procurement Quota Increase Request Hydrocodone (DFN:630-08.2)	Date  <p style="text-align: center;">FEB 03 2011</p>
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To  
 Christine A. Sannerud, Ph.D, Chief  
 Drug & Chemical Evaluation Section  
 Office of Diversion Control

From *[Signature]*  
 Barbara J. Boockholdt, Chief  
 Regulatory Section  
 Office of Diversion Control

On January 31, 2011, this section received your memorandum requesting a review of (b)(4) 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) of (b)(4) customers as well as on (b)(4)

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

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

- Retired 11/17/2010
- Currently Under Review/Investigation
- 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 (b)(4) for the quota increase.

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)

# Memorandum



Subject

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

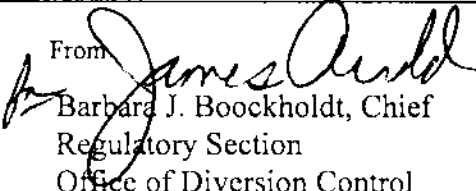
Date

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)

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

## QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

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

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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

# Memorandum



2/13/11  
(b)(6);(b)(7)(C)

Subject Quota Letters Received as of February 10, 2011 (DFN: 630-08.2)	Date  <b>FEB 14 2011</b>
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To  
Christine A. Sannerud, Ph.D., Chief  
Drug & Chemical Evaluation Section  
Office of Diversion Control

From  
*Barbara J. Bockholdt*  
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)

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



Mylan Technologies (11118)  
Sandoz (Geneva Pharmaceuticals, Inc) (11119)  
Novartis Consumer Health Lincoln (11120)  
King Pharmaceuticals (11121)  
Mallinckrodt St. Louis (11122)  
Chattem (11123)

(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 (b)(6);(b)(7)(C) or SC

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

# 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

*Bar* 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.

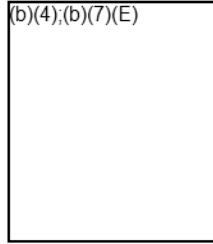
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

## QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

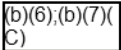
Fisher Clinical Services (11125)  
Fisher Clinical Services (11126)  
Barr Labs (11127)  
Cambrex (11128)  
AAI Pharma Services (11129)  
Sigma-Aldrich Services (11130)  
Sigma-Aldrich Services (11131)  
Specialty Compounding (11132)  
Specialty Compounding (11133)  
Specialty Compounding (11134)  
Specialty 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)

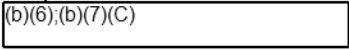
(b)(4);(b)(7)(E)

Johnson Matthey (11148)  
Barr Laboratories (11149)  
Barr Laboratories (11150)  
Upsher-Smith (11151)  
Norac Inc (11152)  
AAI Pharma 1726 N. 23<sup>rd</sup> St (11153)



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



<p>Subject</p> <p>Quota Letters Received as of February 17, 2011 (DFN: 630-08.2)</p>	<p>Date</p> <p>FEB 23 2011</p>
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To

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

From *James Arnold*  
for 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)

(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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

# Memorandum



Subject Quota Request as February 25, 2011 (DFN: 630-08.2)	Date March 4, 2011
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To  
Christine A. Sannerud, Ph.D., Chief  
Drug & Chemical Evaluation Section  
Office of Diversion Control

From *James Aull*  
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

Log In #	Company Name	Registration #
11174	Alere San Diego	<span style="border: 1px solid black; padding: 5px;">(b)(4);(b)(7)(E)</span>
11175	Qualitest	
11176	Fisher Clinical Services	
11177	Almac Clinical Services	
11178	GSMS	
11180	Mallinckrodt St. Louis	
11181	ANI Pharmaceuticals, Inc.	
11183	OHM Labs	
11184	Corium	
11186	Sure-Tech	
11187	Archimica	
11188	Nexgen Pharma, Inc.	
11189	DPT Paco Way	


11190 Siegfried  
11191 Siegfried


(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 (b)(6);(b)(7)(C) Chief/ODGR at (b)(6);(b)(7)(C)

Cc: ChristineASannerud, PhD/Chief/ODE/Drug&ChemicalEvaluationSection

Cc: ODG  3/4/11

Cc: ODGR  (b)(6);(b)(7)(C) 3/4/2011:ReqDoc2/25/2011

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

**From:** (b)(6);(b)(7)(C)  
**Sent:** Friday, February 25, 2011 3:39 PM  
**To:** (b)(6);(b)(7)(C)  
**Subject:** RE: Quota Letters Received as of February 25, 2011

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

The correct registration number for Qualitest (AKA Vintage) is (b)(4);(b)(7)(E)

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

**From:** (b)(6);(b)(7)(C)  
**Sent:** Friday, February 25, 2011 3:09 PM  
**To:** (b)(6);(b)(7)(C)  
**Cc:** (b)(6);(b)(7)(C); Boockholdt, Barbara J.; (b)(6);(b)(7)(C)  
**Subject:** RE: Quota Letters Received as of February 25, 2011  
**Importance:** High

11175 Qualitest

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

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

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

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

**Program Analyst  
Regulatory Unit - ODGR**

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

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

**From:** (b)(6);(b)(7)(C)  
**Sent:** Friday, February 25, 2011 10:07 AM



To: (b)(6);(b)(7)(C)  
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.  
Subject: FW: Quota Letters Received as of February 25, 2011

(b)(6);(b)(7)(C) (b)(6);(b)(7)(C)  
Please see attached quota reviews. (b)(6);(b)(7)(C) will be away for another week or two.

Thanks!

(b)(6);(b)(7)(C)  
Chief, Regulatory Unit/ODGR  
DEA Headquarters  
(b)(6);(b)(7)(C) (Office)  
(b)(6);(b)(7)(C) (Fax)  
(b)(6);(b)(7)(C) (Blackberry)  
(b)(6);(b)(7)(C) @usdoj.gov

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From: (b)(6);(b)(7)(C)  
Sent: Friday, February 25, 2011 10:04 AM  
To: Boockholdt, Barbara J.; (b)(6);(b)(7)(C) (b)(6);(b)(7)(C)  
Cc: Sannerud, Christine A.; (b)(6);(b)(7)(C) (b)(6);(b)(7)(C) Hill, Robert L.  
Subject: Quota Letters Received as of February 25, 2011

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.

Log In #	Company Name	Registration #
11174	Alere San Diego	(b)(4);(b)(7)(E)

- 11175 Qualitest
- 11176 Fisher Clinical Services
- 11177 Almac Clinical Services
- 11178 GSMS
- 11180 Mallinckrodt St. Louis  
ANI Pharmaceuticals,  
11181 Inc.
- 11183 OHM Labs
- 11184 Corium
- 11186 Sure-Tech
- 11187 Archimica
- 11188 Nexgen Pharma, Inc.
- 11189 DPT Paco Way
- 11190 Siegfried
- 11191 Siegfried

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

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

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

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

# Memorandum



Subject Quota Request as February 28, 2011 (DFN: 630-08.2)	Date  MAR 04 2011
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To

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

From *James Auld*  
for 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

Log In #	Company Name	Registration #
11193	KVK Tech, Inc.	(b)(4);(b)(7)(E)
11194	Mylan Pharmaceuticals	
11195	Mylan Pharmaceuticals	
11196	Siegfried PD-RX	
11211	Pharmaceuticals	
11212	Penick Corp	
11213	Fisher Clinical	

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 (b)(6);(b)(7)(C) Chief/ODGR at (b)(6);(b)(7)(C)

Cc: ChristineASannerud,PhD/Chief/ODE/Drug&ChemicalEvaluationSection

Cc: ODG 

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

Cc: ODGR 

3/4/2011:ReqDoc2/28/2011

