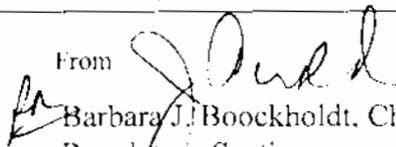


Memorandum



Subject Additional Quota Letters Received by July 15, 2010 (DFN: 630-08.2)	Date JUL 16 2010
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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 July 15, 2010, this section received your e-mail requesting a review of seventeen (17) 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

Novartis Consumer Health Lincoln (10345)
Baxter (10346)
Generics Bideo II bda Vintage (10347)
Noramco Delaware (10348)
Pharmaceuticals International Inc. (10349)
Pharmedium (10351)
Pharmedium (10352)
Rhodes (10356)
Bio-Pharm (10357)
Patheon (10358)
Patheon (10359)
Watson (10361)
B & B (10363)
Hospira, Inc. NC (10364)
Epic Pharma (10366)
Mallinckrodt Hobart (10367)
Chemtos (10368)

(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

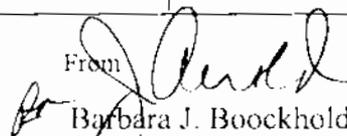


Subject Additional Quota Letters Received as of July 19, 2010 (DFN: 630-08.2)	Date JUL 28 2010
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To

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 July 19, 2010, this section received your e-mail requesting a review of six (06) quota applications to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

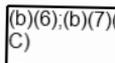
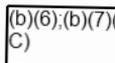
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

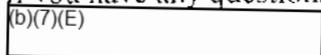
QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Sigma Aldrich (10370)
Emerson (10372)
Watson (10373)
Catalent (10374)
Akorn dba Taylor (10375)
Akorn dba Taylor (10376)

(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



Subject

Additional Quota Letters as of July 30, 2010
(DFN: 630-08.2)

Date

AUG 25 2010

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 July 30, 2010, this section received your e-mail requesting a review of forty-five (45) quota applications from twenty-four (24) 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

DSM (10378)
Siegfried (10380)
Chemtos (10381)
Fisher Virginia (10382)
Fisher Virginia (10383)
Fisher Virginia (10384)
Cambrex (10385)
Purdue North Carolina (10385)
Purdue North Carolina (10387)
AustarPharma (10390)
AustarPharma (10391)
Letco Medical (10392)
Norameco Georgia (10393)
Johnson Matthey (10394)
Johnson Matthey (10395)
Johnson Matthey (10396)
Johnson Matthey (10397)
Johnson Matthey (10398)
Johnson Matthey (10399)
Johnson Matthey (10400)

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

Johnson Matthey (10402)
 Johnson Matthey (10403)
 Johnson Matthey (10404)
 Johnson Matthey (10405)
 AAI (10406)
 Barr Virginia (10407)
 Noramco Delaware (10408)
 DSM (10409)
 Mallinckrodt St. Louis (10411)
 Janssen Cilag (10412)
 Almac (10413)
 Mallinckrodt St. Louis (10414)
 Alza Vacaville (10416)
 Johnson Matthey (10417)
 Hospira, Inc NC (10418)
 DSM (10419)
 Cambrex (10420)
 Barr (10421)
 Noramco (10424)
 Noramco (10425)
 Noramco (10426)
 Bilcare (10427)
 Mallinckrodt St. Louis (10428)
 Halo (10429)
 Siegfried (10430)

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

Per consultation with the field office, 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)

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

Memorandum



Subject Additional Quota Letters Received as of August 16, 2010 (DFN: 630-08.2)	Date SEP 01 2010
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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 August 16, 2010, this section received your e-mail requesting a review of forty-five (45) quota applications from thirty-eight (38) 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

- CorePharma Wood Ave (10434)
- Noramco Georgia (10437)
- Elan Holdings (10439)
- Roxane Oak Street (10440)
- Bilcare Global Clinical Supplies (10441)
- Vintage Generics Bidco (10443)
- Noramco Delaware (10444)(1 of 2)
- Micron Twchnologies, Inc ((10444)(2 of 2)
- Fisher Virginia ((10445)
- Hospira Inc KS (10446)
- Boehringer Ingelheim (10447)
- Purdue North Carolina (10448)
- Amneal - Brookhaven (10449)
- Med-Pharmex (10452)
- Janssen Puerto Rico (10453)
- AMRI (10454)
- PCCA (10455)
- Patheon (10456)
- Noramco Delaware (10457)
- Aptuit (10458)

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

Norwich (10459)
 Catalent Pharma Solutions (10468)
 Watson New Jersey (10469) (1 of 2)
 Watson New Jersey (10469) (1 of 2)
 Hisamitsu California Laboratories (10470)
 Hisamitsu California Laboratories (10471)
 Noramco Georgia (10472)
 Fisher Pennsylvania (10473)
 Amneal – Brookhaven (10474)
 Watson Laboratories, Inc (10478) (1 of 2)
 Watson Laboratories, Inc (10478) (2 of 2)
 Sun New Jersey (10479)
 DSM (10480) (1 of 2)
 DSM (10480) (2 of 2)
 Cambrex (10482)
 UCB Manufacturing (formerly Celitech NY) (10483)
 Palmetto State Pharmaceuticals (10485)
 Ortho McNeil Pharmaceutical (10486)
 Bilcare (10487)
 Noramco Delaware (10488)
 Pii (10489) (1 of 2)
 Pii (10489) (2 of 2)
 Catalent Pharma Solutions (19456)

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

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

Currently Under Review/Investigation

Per consultation with the field office, 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)

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

Memorandum



Subject Additional Quota Letters Received as of August 26, 2010 (DFN: 630-08.2)	Date SEP 01 2010
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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 August 26, 2010, this section received your e-mail requesting a review of forty-one (41) quota applications from thirty-two (32) 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 (10491)
- Corium (10492)
- Novartis (10493)
- DPI Paco Way (10494)
- United Liquid, Inc. (10495)
- King Pharmaceuticals (10496)
- Barr Virginia (10497)
- ANI Pharmaceuticals, Inc (10498)
- AustarPharma (10499) (1 of 2)
- AustarPharma (10499) (2 of 2)
- Cima Brooklyn Park (10501)
- Cima Brooklyn Park (10502)
- Noramco Delaware (10503)
- King (10504)
- Barr Virginia (10505)
- Sun New Jersey (10506)
- Novartis Consumer Health Lincoln (10507)
- Diamond Animal (10508)
- Fisher Pennsylvania (10509)
- Cerilliant (10510)

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

- Pharmaceutics International (10511)
- Chattem (10512)
- Boehringer Ingelheim (10513)
- Barr Virginia (10514)
- Unique Pharmaceuticals (10515)
- King (10517)
- Mallinckrodt St. Louis (10518)
- Ohm (10519)
- Norac, Inc. (10521)
- Nucare Pharmaceuticals (10522)
- Ohm (10529)
- Watson Pharmaceuticals (10530) (1 of 2)
- Watson Pharmaceuticals (10530) (2 of 2)
- Patheon (10531)
- Watson Pharmaceuticals (10534) (1 of 2)
- Watson Pharmaceuticals (10534) (2 of 2)
- Watson Pharmaceuticals (10535) (1 of 2)
- Watson Pharmaceuticals (10535) (2 of 2)
- Impax Pennsylvania (10536)
- Purdue North Carolina (10537)
- Aurolife Pharma (10538)

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

Per consultation with the field office, 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 Letters Received as of September 13, 2010
(DFN: 630-08.2)

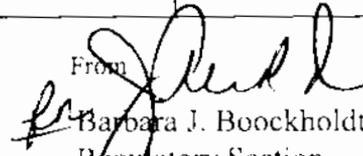
Date

SEP 29 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 September 13, 2010, this section received your e-mail requesting a review of forty-eight (48) quota applications from thirty-eight (38) 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

Great Southern (10540)
Tris Pharma, Inc. (10541)
Mallinckrodt St. Louis (10542)
Mallinckrodt St. Louis (10543)
VistaPharm (10544)
Ameridose, LLC (10547)
Metrics (10549)
Central Admixture – San Diego (10552)
Central Admixture – San Diego (10553)
Siegfried (10554)
Mallinckrodt (10555)
Mallinckrodt (10556)
Noramco Delaware (10558)
Mallinckrodt St. Louis (10559)
Purdue North Carolina (10560)
Mylan Chestnut Ridge Road, West Virginia (10561)
Cedarburg (10562)
Hospira, Inc. (10563)
PCCA (10564)
Southwest Research Institute (10565)

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

Vintage Pharmaceuticals (10566)
 Vintage Pharmaceuticals (10567)
 Tedor Pharma Inc. (10569)
 Mallinckrodt (10571)
 Corium (10572)
 KV Pharmaceutical (10573)
 KV Pharmaceutical (10573)(2 of 3)
 KV Pharmaceutical (10573)(3 of 3)
 Chemtos (10574)
 Gallipot, Inc. (10575)
 Lannett Co., Inc. (10576)
 Epic Pharma, LLC (10577)
 Archimica (10578)
 Mylan (10579)
 Boehringer Ingelheim (10580)
 B&B Pharmaceuticals (10582)
 B&B Pharmaceuticals (10583)
 Barr Laboratories (10584)
 Barr Laboratories (10585)
 Ohm (10586)
 Hospira, Inc. (10587)
 Actavis Elizabeth (10588)
 AMRI (10590)
 AMRI (10591)
 Boehringer Ingelheim (10592)
 Siegfried (10594)
 King (10595)
 Schwarz (10597)

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

Per consultation with the field office, 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)

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

Memorandum



Subject Additional Quota Letters Received as of September 21, 2010 (DFN: 630-08.2)	Date SEP 29 2010
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To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

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

On September 21, 2010, this section received your e-mail requesting a review of thirty-two (32) quota applications from twenty-eight (28) 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

- Noramco, Inc (10600)
- Nexgen Pharma, Inc (10601)
- Bend Research, Inc (10603)
- ANI Pharmaceuticals, Inc (10604)
- Generies Bideo II (10605)
- Vintage Pharmaceuticals (10606)
- Metrics (10607)
- Catalent Pharma Solutions (10608)
- PCCA (10609)
- Halo Pharmaceutical (10610)
- Novartis Consumer Health Lincoln (10611)
- Bilcare (10612)
- Norwich Pharmaceuticals (10617)
- Austar Pharma LLC (10618)
- Ohm Laboratories (10619)
- Fisher Clinical Services (10620)
- Fisher Clinical Services (10621)
- Nexgen Pharma, Inc (10622)
- Hospira, Inc (10623)
- Covidien (10624)

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

PII (10625)
Hospira, Inc (10631)
Fisher Clinical Services (10632)
Fisher Clinical Services (10633)
Fisher Clinical Services (10634)
Coating Place Inc (10635)
Cerilliant (10636)
Epic Pharma (10637)
Siegfried (10638)
Patheon (10639)
Watson Connecticut (10640)
Mylan Pharmaceuticals (10641)

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

Per consultation with the field office, 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 October 4, 2010 (DFN: 630-08.2)	Date OCT 05 2010
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To
Christine A. Samnerud, 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 October 4, 2010, this section received your e-mail requesting a review of twenty-three (23) quota applications from twenty-one (21) 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

- ✓ Pharmedium (10653)
- ✓ Pharmedium (10654)
- ✓ AustarPharma, LLC (10656)
- ✓ Janssen Cilag (10666)
- ✓ Sigma-Aldrich Research Biochemicals (10667)
- ✓ Ohm (10668)
- ✓ PCCA ((10674)
- ✓ Barr Laboratories, Inc. (10677)
- ✓ Barr Laboratories, Inc. (10678)
- ✓ Shire (10679)
- ✓ Dispensing Solutions, Inc. (10680)
- ✓ Watson Laboratories, Inc. (10681)
- ✓ Watson Laboratories, Inc. (10681)(2 of 2)
- ✓ UCB Manufacturing (formerly Celltech NY)(10682)
- ✓ Classic (10683)
- ✓ AMRI (10685)
- ✓ Noramco, Inc. (10686)
- ✓ PCCA (10687)
- ✓ Actavis South-Atlantic (10690)
- ✓ Pii (10691)

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

- ✓ Noramco Delaware (10692)
- ✓ Noramco Delaware (NA009) (1 of 2)
- ✓ Noramco Georgia (NA009 (2 of 2)

(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)

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

Memorandum



10/14/10

Subject Quota Letters Received as of October 8, 2010 (DFN: 630-08.2)	Date OCT 14 2010
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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 October 8, 2010, this section received your e-mail requesting a review of twenty-two (22) quota applications from twenty-one (21) 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

- Tris Pharma, Inc. (10657)
- Anazao Health (10658)
- Elan Holdings (10660)
- Safecor Health, LLC (Regional Service Center)(10661)
- Pfizer, Inc (10662)
- Aurolife Pharma LLC (10663)
- AAI Pharma, Inc. (10664)
- Sharp Corporation (10665)
- Restek (10694)
- Hospira, Inc. (10695)
- Amneal - Brookhaven (10696)
- Rhodes (10697)
- DPT (10698)
- Novartis Consumer Health Lincoln (10699)
- Actavis South-Atlantic (10701)
- Anazao Health (10702)
- Mylan Technologies (10704)
- VistaPharm (10705)
- Covidien (10707)

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

Barr Laboratories (10708)
Noramco (10709)
Catalent (10710)

(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 Letter Received (DFN: 630-08.2)	Date OCT 14 2010
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To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

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

On October 12, 2010, this section received your e-mail requesting a review of one (1) quota application from a registered manufacturer to determine if there are any pending administrative/legal actions against this applicant and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

UCB Manufacturing (formerly Celltech NY) (10682) (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 October 14, 2010
(DFN: 630-08.2)

Date

OCT 20 2010

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 October 14, 2010, this section received your e-mail requesting a review of twenty-four (24) quota applications from twenty-one (21) 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 Pharma (10718)
Fisher Clinical (10719)
Shire (10720)
DSM (10721)
Patheon (10722)
Hospira, Inc. (10723)
AAIPharma Services (10724)
Tris Pharma, Inc. (10725)
Cody Labs (10726)
Cody Labs (10727)
Coating Place Inc. (10728)
Taylor Pharmaceuticals (10729)
Restek (10730)
DSM (10731)
Patheon (10732)
Aptuit (10733)
Spectrum (10734)
Aptuit (10735)
Norac, Inc. (10739)
Sandoz (formerly Geneva Pharma) (10740)

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

Medisca, Inc. (10741)
TEVA (10742)
Fisher Clinical Services (10743)
Janssen Cilag (10744)

(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)

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

Memorandum



Subject

Initial 2010 Manufacturing Quota Letters
DFN:630-08.2

Date

OCT 21 2009

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 October 15, 2009, this section received your e-mail requesting a review of twenty-four (24) 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 advisement. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Alltech Associates
American Radiolabeled Chemicals
AMRI Rensselaer, Inc.
Archimica, Inc.
Austin Pharma, Inc.
Boehringer Ingelheim
Cambrex Charles City, Inc.
Cayman Chemical
Cerilliant
Chattem Chemicals, Inc.
Chemtos, I.L.C.
Halo
Johnson Matthey
Johnson Matthey Pharmaceutical Materials
Lonza
Mallinckrodt St. Louis
Norac, Inc.
Noramco Delaware
Noramco Georgia
Penick Corporation

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

Rhodes Technologies
Siegfried
Siemens Healthcare Diagnostics Inc.
Stephan

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

Per consultation with the field office, 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 twenty-four (24) 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 October 18, 2010 (DFN: 630-08.2)	Date OCT 20 2010
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To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

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

On October 18, 2010, this section received your e-mail requesting a review of three (03) 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

Covidien (10750)
Janssen Cilag (10751)
Baxter (10752)

(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.

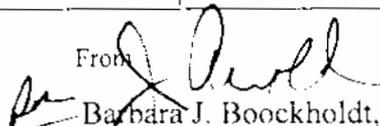
If you have any questions pertaining to this information, please feel free to contact me (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

Memorandum



Subject Quota Letters Received as of October 21, 2010 (DFN: 630-08.2)	Date OCT 26 2010
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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 October 21, 2010, this section received your e-mail requesting a review of twenty-three (23) quota applications from sixteen (16) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODI of the findings.

ODGR conducted reviews (NAADDIS, 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-Services (10754)
- PCCA (10755)
- Tris Pharma, Inc. (10756)
- Covidien (10757)
- Corepharma LLC (10758)
- Corepharma LLC (10759)
- Covidien (10761)
- Covidien (10762)
- Patheon (10766)
- Patheon (10767)
- Watson (10768)
- Baxter (10769)
- Epic Pharma (10770)
- Cerilliant (10771)
- AustarPharma (10780)
- Cima Brooklyn Park (10781)
- Cima Brooklyn Park (10782)
- Barr Laboratories (10783)
- Johnson Matthey (10784)
- Colorcon (10785)

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

AAI Pharma Services (10786)
Covidien (10787)
Covidien (10788)

(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 October 28, 2010 (DFN: 630-08.2)	Date OCT 29 2010
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To
Christine A. Sannerud, Ph.D., Chief
Drug & Chemical Evaluation Section
Office of Diversion Control

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

On October 28, 2010, this section received your e-mail requesting a review of twelve (12) 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

- Ameridose, LLC (10794) (1 of 2)
- Ameridose, LLC (10794) (2 of 2)
- Archimica (10795)
- Bio-Pharma (10799)
- Cambrex (10792)
- Cerilliant (10791)
- Covidien (10793)
- Johnson Matthey (10790)
- PharmaForm (10796)
- Rhodes (10797)
- Sandoz (formerly Geneva Pharmaceuticals, Inc) (10798)
- VistaPharm (10789)

(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 November 1, 2010 (DFN: 630-08.2)	Date NOV 05 2010
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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 November 1, 2010, this section received your e-mail requesting a review of nine (09) 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

- Metrics (10800)
- Taylor Pharmaceuticals (10801)
- AAI Pharma Services (10802)
- AustarPharma (10803)
- Bio-Pharm (10804)
- Halo Pharma (10806)
- Mikart (10807)
- Mikart (10807) (2 of 2)
- Vortech (10809)

(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

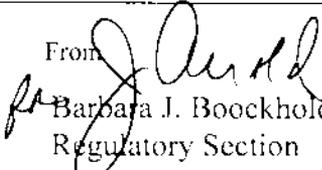


Subject	Date
Quota Letters Received as of November 8, 2010 (DFN: 630-08.2)	NOV 09 2010

To

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

From

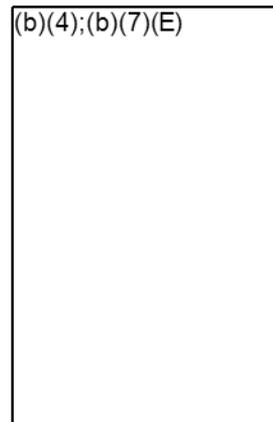

Barbara J. Boockholdt, Chief
Regulatory Section
Office of Diversion Control

On November 8, 2010, this section received your e-mail requesting a review of ten (10) quota applications to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

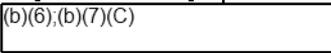
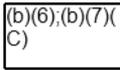
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Sun Pharmaceuticals (10672)
Formurex (10738)
Janssen Cilag (10751)(1 of 2)
Elan Holdings (10817)
Noramco (10819)
Pii (10820)
Medisca (10821)
Tris Pharma, Inc. (10822)
Novartis Consumer Health Lincoln (10824)
Covidien (10832)



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

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

2010 Procurement Quota Increase Request
Hydrocodone
(DFN:630-08.2)

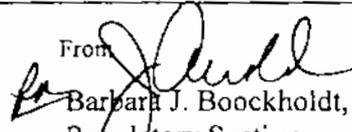
Date

NOV 09 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 November 5, 2010, this section received your memorandum requesting a review of the (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 sixty-eight (168) 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 05/21/2010
Currently Under Review/Investigation
Currently Under Order to Show Cause
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 (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

Memorandum



Subject

Quota Letters Received as of November 12, 2010
(DFN: 630-08.2)

Date

NOV 16 2010

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 November 12, 2010, this section received your e-mail requesting a review of seven (07) 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

Nexgen Pharma, Inc (10811)
Watson (10812)
Boehringer Ingelheim (10816)
Johnson Matthey (10834)
Novartis Consumer Health Lincoln (10835)
AMRI (10836)
Catalent (10837)

(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)

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

Memorandum



Subject

Quota Letters Received as of November 18, 2010
(DFN: 630-08.2)

Date

NOV 19 2010

To

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

From

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

On November 18, 2010, 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

Aptuit, Inc. (10735s)
Elan Holdings (10749)
Novartis (10808)
Watson (10845)
Novartis (10846)
Par Pharmaceutical (10847)
Rhodes Technologies (10849)
Barr Laboratories (10850)
CoreRx Inc. (10851)
AustarPharma (10852)
Mylan Technologies (10853)
GPSG (10854)
Tedor Pharma Inc. (10855)
Covidien (10858)
KVK-Tech Inc. (10859)
Catalent Pharma Solutions (10861)
Sharp Corporation (10862)
AAI Pharma Services (10863)
AnazaoHealth (10864)

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

Per consultation with the field offices, DIA 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)

2010 Procurement Quota Increase Request
Hydrocodone
(DFN:630-08.2)

Date

NOV 19 2010

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 November 17, 2010, this section received your memorandum requesting a review of the (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.

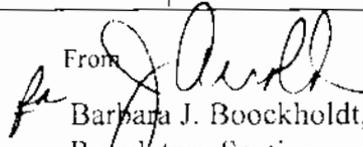
If you have any questions pertaining to this information, please feel free to contact me (b)(6);(b)(7)(C) or SC (b)(6);(b)(7)(C)

Memorandum



Subject Quota Letters Received as of November 29, 2010 (DFN: 630-08.2)	Date NOV 30 2010
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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 November 29, 2010, this section received your e-mail requesting a review of seven (07) quota applications to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

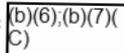
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

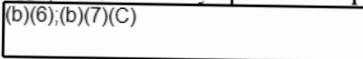
QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis (10870)
Cody Labs (10876)
DPT (10872)
Endo Pharmaceutical (10873)
Mylan (10874)
Watson (10875)
Watson (10875) (2 of 2)

(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 

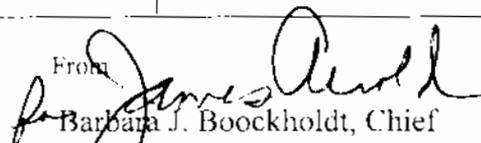


Memorandum



Subject Quota Letters Received as of December 6, 2010 (DFN: 630-08.2)	Date DEC 07 2010
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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 December 6, 2010, this section received your e-mail requesting a review of nine (09) quota applications to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

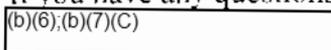
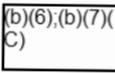
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

- Vintage Pharmaceuticals (10877)
- Olay (10878)
- Noramco Delaware (10879)
- Catalent Pharma Solutions (10880)
- AustarPharma (10882)
- Halo Pharmaceutical Company (10885)
- AAI Pharma (10886)
- Safecor Health, LLC (Regional Service Center (10887)
- Qualitest (10888)

(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 Decemer 10, 2010
(DFN: 630-08.2)

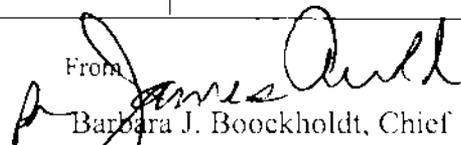
Date

DEC 14 2010

To

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

From


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

On December 10, 2010, 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.

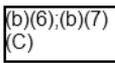
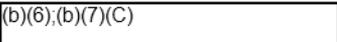
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Noramco (10892)
King Pharmaceuticals (10893)
Amneal Pharmaceuticals (10894)
Cephalon, Inc. (10895)
AAI Pharma (10899)

(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



Subject

Quota Letters Received as of Decemer 13, 2010
(DFN: 630-08.2)

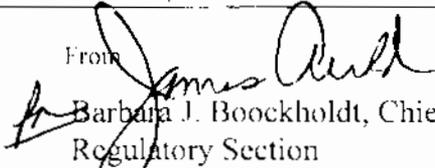
Date

DEC 14 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 December 13, 2010, this section received your e-mail requesting a review of six (06) quota applications to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

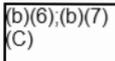
ODGR conducted reviews (NAADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Noramco (10892)
Amneal Pharmaceuticals (10894)
Cephalon, Inc. (10895)
King Pharmaceuticals (10896)
AAI Pharma (10899)
AMRI Rensslear, Inc. (10903)

(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



Subject

Quota Requests as of December 14, 2010
(DFN: 630-08.2)

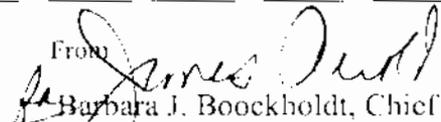
Date

December 20, 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 December 14, 2010, this section received your e-mail requesting a review of two-hundred and thirty-one (231) 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 (CSA, etc), as well as surveyed the responsible field offices as needed for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

IMQ001	Alltech Associates
IMQ002	AMRI Rensselaer
IMQ003	Archimica
IMQ004	Austin Pharma
IMQ005	Cambrex
IMQ006	Cayman Chemical
IMQ007	Boehringer Ingelheim
IMQ008	Cerilliant
IMQ009	Chattem
IMQ010	Cody

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

- IMQ011 Halo Pharmaceutical Inc.
- IMQ012 Johnson Matthey
- IMQ013 Johnson Matthey Pharmaceutical
Materials
- IMQ014 Johnson Matthey Pharmaceutical
Materials
- IMQ015 Mallinckrodt St. Louis
- IMQ016 Norac, Inc.
- IMQ017 Noramco
- IMQ018 Noramco
- IMQ019 Penick
- IMQ020 Rhodes
- IMQ021 Siegfried
- IMQ022 Siemens Healthcare Diagnostics Inc.
- IMQ023 Stepan
- IMQ024 American Radiolabeled Chemicals
- IMQ025 Cedarburg
- IMQ026 Lonza
- IMQ027 Chemica Inc.
- IMQ028 ElSohiy Laboratories, Inc.
- IPQ001 AAIPharma Services Corp.
- IPQ002 Actavis Elizabeth LLC
- IPQ003 Advanced Pharma
- IPQ004 Alltech Associates
- IPQ005 Almac Clinical Services
- IPQ006 Altea Therapeutics
- IPQ007 Arista Biologicals

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

IPQ008 B & B
IPQ009 Banyan International Corporation
IPQ010 Barr Laboratories, Inc.
IPQ011 Barr Laboratories, Inc.
IPQ012 Baxter Healthcare Corporation
IPQ013 Biochemical Diagnostics, Inc.
IPQ014 Bio-Rad Laboratories
IPQ015 Biosite
IPQ016 Boehringer Ingelheim
IPQ017 Boehringer Ingelheim Vetmedica, Inc.
IPQ018 Boehringer Ingelheim Roxane, Inc.
IPQ019 Cambrex Charles City
IPQ020 Cardinal Health
IPQ021 Catalent Pharma Solution
IPQ022 Catalent Pharma Solution
IPQ023 Cephalon, Inc.
IPQ024 Cephalon, Inc.
IPQ025 Cephalon, Inc.
IPQ026 Cerilliant
IPQ027 Chattem
IPQ028 Chemtos
IPQ029 CIMA Labs, Inc.
IPQ030 CIMA Labs, Inc.
IPQ031 Classic Pharmaceuticals, LLC
IPQ032 Cody Laboratories, Inc.

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

- IPQ033 Consolidated Technologies
- IPQ034 CorePharma, LLC
- IPQ035 Dispensing Solutions, Inc.
- IPQ036 DPT Lakewood, Inc.
- IPQ037 DSM Pharmaceuticals, Inc.
- IPQ038 Elan Holdings
- IPQ039 Elge, Inc.
- IPQ040 Endo Pharmaceuticals, Inc.
- IPQ041 Epic Pharma LLC
- IPQ042 Gallipot
- IPQ043 Great Southern Laboratories
- IPQ044 Halo Pharmaceutical, Inc.
- IPQ045 Diamond Animal Health, Inc.
- IPQ046 Hi-Tech Pharmacal Co. Inc.
- IPQ047 Hospira, Inc.
- IPQ048 Hospira, Inc.
- IPQ049 Impax Laboratories, Inc.
- IPQ050 Impax Laboratories, Inc.
- IPQ051 Impax Laboratories, Inc.
- IPQ052 Abbott Laboratories North Chicago
- IPQ053 Actavis
- IPQ054 Akorn
- IPQ055 Akorn
- IPQ056 Alza Corporation
- IPQ057 Ameridose, LLC

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

IPQ058 Ameridose, LLC
IPQ059 AstraZeneca
IPQ060 Banner Pharmacaps
IPQ061 BD medical
IPQ062 Bio-Pharm
IPQ063 Cantrell Drug Company
IPQ064 Catalent
IPQ065 Corium
IPQ066 Clinical Supplies Management
IPQ067 Elite Laboratories
IPQ068 Generics Bidco II dba Vintage
IPQ069 International Medication
IPQ070 Janssen Cilag
IPQ071 Janssen Ortho
IPQ072 Johnson Matthey
IPQ073 King Pharmaceuticals
IPQ074 KV Pharmaceuticals
IPQ075 KV Pharmaceuticals
IPQ076 KV Pharmaceuticals
IPQ077 Lehigh Valley Technologies, Inc.
IPQ078 Letco Medical
IPQ079 Mallinckrodt St. Louis
IPQ080 Mallinckrodt Hobart
IPQ081 Med-Pharmex
IPQ082 Medisca

(b)(4),(b)(7)(E)

IPQ083 Metrics
IPQ084 Micron Technologies, Inc.
IPQ085 Mikart Inc.
IPQ086 Mikart Inc.
IPQ087 Morton Grove Pharmaceuticals, Inc.
IPQ088 Mylan Technologies
IPQ089 Nexgen Pharma, Inc.
IPQ090 Noramco Delaware
IPQ091 Noramco Georgia
IPQ092 Norwich Pharmaceuticals
IPQ093 Novartis
IPQ094 Novartis
IPQ095 Novartis Consumer Health Lincoln
IPQ096 Novel Laboratories
IPQ097 Noven
IPQ098 NuCare
IPQ099 Ohm Laboratories
IPQ100 Ohm Laboratories
IPQ101 Olay LLC
IPQ102 Pacira Pharmaceuticals
IPQ103 Pacira Pharmaceuticals
IPQ104 Paddock Laboratories
IPQ105 PalliRx, Inc.
IPQ106 Patheon
IPQ107 Penick

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

IPQ108 Pharmaceutical Associates
Pharmaceutical Manufacturing
IPQ109 Research Services, Inc.
IPQ110 Pharmaceuticals International, Inc.
IPQ111 Pharmacia & Upjohn
IPQ112 Pharmedium
IPQ113 Pharmedium
IPQ114 Physicians Total Care
IPQ115 Purdue
IPQ116 Purdue
IPQ117 Quality Assurance
IPQ118 Research Triangle Institute
IPQ119 Restek
IPQ120 Rhodes
IPQ121 Roche
IPQ122 Safecor
IPQ123 Sandoz
IPQ124 Schwarz Pharma Manufacturing
IPQ125 Siegfried
IPQ126 Siemens Healthcare Diagnostics Inc.
IPQ127 Sigma Aldrich
IPQ128 Sigma Aldrich
IPQ129 Spectrum
IPQ130 Stepan
IPQ131 St. Mary's Medical Park Pharmacy
IPQ132 Sun Pharmaceuticals

(b)(4),(b)(7)(E)

- IPQ133 Sun Pharmaceuticals
- IPQ134 Teva Pharmaceuticals
- IPQ135 UCB Manufacturing (formerly Celltech NY)
- IPQ136 Unique Pharmaceuticals
- IPQ137 Varian
- IPQ138 Vintage
- IPQ139 Vintage
- IPQ140 VistaPharm
- IPQ141 Watson
- IPQ142 Watson
- IPQ143 Watson
- IPQ144 Watson
- IPQ145 Watson
- IPQ146 Amneal - Brookhaven
- IPQ147 Amneal - Hauppauge
- IPQ148 Cima Brooklyn Park
- IPQ149 Cima Eden Prairie
- IPQ150 Palmetto State Pharmaceuticals
- IPQ151 AmeriSource Ohio
- IPQ152 Sharp Corporation
- IPQ153 Elite
- IPQ154 3M West Water Street
- IPQ155 Bryant Ranch Prepack
- IPQ156 Central Admixture - San Diego
- IPQ157 Central Admixture - Denver

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

IPQ158 Boehringer Ingelheim
IPQ159 Anderson Packaging, Inc
IPQ160 AAI 1726 North 23rd
IPQ161 Actavis Mid-Atlantic
IPQ162 AMRI Rensselaer, Inc
IPQ163 Alaunus Pharmaceutical, Inc
IPQ164 American Radiolabeled Chemicals
IPQ165 Bend Research
IPQ166 Med Shop Total Care
IPQ167 Core Tech Solutions, Inc.
IPQ168 Cerovene
IPQ169 Durect
IPQ170 Fisher - Bristol, PA
IPQ171 Jerome Stevens
IPQ172 Catalent Pharma
IPQ173 Fisher Pennsylvania
IPQ174 AAI pharma
IPQ175 AAI pharma
IPQ176 Amneal
IPQ177 Anazao Health
IPQ178 Aptuit, Inc
IPQ179 Aveva Drug Delivery (formerly Elan Transdermal)
IPQ180 Eisohly Laboratories, Inc.
IPQ181 Formurex, Inc.
IPQ182 Lannett

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

- IPQ183 Mylan
- IPQ184 Ortho McNeil Pharmaceutical
- IPQ185 Par
- IPQ186 Par
- IPQ187 PD-RX Pharmaceuticals
- IPQ188 PCCA
- IPQ189 P.F. Laboratories
- IPQ190 PrePak Systems
- IPQ191 Sandoz
- IPQ192 Sovereign
- IPQ193 Tris Pharma, Inc.
- IPQ194 Watson
- IPQ195 Pharmaceuticals International, Inc.
- IPQ196 Lannett
- IPQ197 LTS Lohmann Therapy System Corp
- IPQ198 Mallinckrodt St. Louis
- IPQ199 Nextar
- IPQ200 GE Healthcare
- IPQ201 Bilcare, Inc.
- IPQ202 West-ward
- IPQ203 Rx Pak

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

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

The company can conduct business as usual with the expired license until a decision is reached on the registration.

Per consultation with the field office, 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)

Memorandum



Subject Quota Letter Received as of December 16, 2010 (DFN: 630-08.2)	Date DEC 17 2010
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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 16, 2010, this section received your e-mail requesting a review of one (1) quota application from a registered manufacturer to determine if there are any pending administrative/legal actions against this applicant and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

USP (10906)

(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



5/

Subject Quota Letter Received as of December 16, 2010 (DFN: 630-08.2)	Date DEC 17 2010
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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

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



FY 2011 PERFORMANCE BUDGET

DRUG ENFORCEMENT ADMINISTRATION

Congressional Budget Submission

U.S. Department of Justice

To achieve this mission, the DCP does the following:

- Identifies and targets those responsible for the diversion of pharmaceutical controlled substances and chemicals through traditional investigative and cyber crime initiatives; and,
- Supports the DEA DCP registrants with improved technology, including the E-Commerce Initiative.

The following strategies outline DEA's plan to achieve these objectives:

Investigate and prepare for prosecution, violators of chemical and pharmaceutical controlled substances laws at the international, national, State, and local levels while maintaining cooperation, support, and assistance from the regulated industry.

Enforcement Activities

DEA has historically utilized Tactical Diversion Squads (TDS) since the late 1970s. These TDSs allow for the unification of separate and sometimes disparate Federal, State, and local information, authorities, and enforcement programs. They work with State and local (S&L) law enforcement authorities in developing more effective enforcement programs against diversion. TDSs also help coordinate with various judicial districts to maximize the effectiveness of multiple investigations and prosecutions of those involved in the diversion of controlled substances and chemicals.

TDSs investigate suspected violations of the CSA and other appropriate Federal or state statutes pertaining to the diversion of licit pharmaceuticals and chemicals. These unique groups combine the resources of DEA (both Special Agents and Diversion Investigators) with S&L law enforcement agencies in an innovative effort to investigate, disrupt and dismantle those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescriptions forgers, and prevalent retail-level violators). TDSs develop sources of information and disseminate intelligence to appropriate elements for the development of leads and targets. The TDS provides support to a Diversion Group and/or a Diversion Staff where law enforcement authority (LEO) activities are required (e.g., purchase of evidence/purchase of information, conducting surveillance, conducting undercover operations, making arrests, and executing search/seizure warrants).

The realignment of DCP personnel into the new TDSs will be accomplished in phases over several years. Phase 1 will implement a basic infrastructure utilizing existing position authorizations, personnel and funding in FY 2009. A full implementation of Phase 2 will require additional budget authority and fee collections.

Additional functions of the DCP include:

- Operational support activities essential to the operation of the above priorities including registration and regulatory support, Diversion Investigator recruitment, training, and drug/chemical surveys; and,

C. Item Name: Diversion Control Program Enforcement and Regulatory Support

Budget Decision Unit(s): Diversion Control Fee Account

Strategic Goal & Objective: Goal II; Objective 2.4

Organization Program: Office of Diversion Control
Special Operation Division

Program Increase: Positions 174 Agents 62 FTE 87 Dollars \$33,508,000

Description of Item

DEA requests \$33,508,000 (including \$4,314,000 in non-personnel funding) and 174 positions (including 62 agents) to address staffing shortfalls at DEA headquarters, Special Operations Divisions (SOD), and in domestic field offices to support. The DOJ Office of Inspector General's (OIG) 2006 report "Follow up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Pharmaceuticals" found that the Diversion Control Program needed to increase law enforcement support to assist the program in performing inherently law enforcement activities. In order to satisfy this requirement, the Diversion Control Program increased its Special Agent authorization by adding 23 new Special Agents in FY 2006; moving 29 existing direct-funded Special Agents to the fee account in FY 2006; and converting 108 vacant Diversion Investigator positions to Special Agents positions in FY 2007. While meeting immediate enforcement needs, the conversion of Diversion Investigator positions to Special Agents has significantly depleted available resources to conduct regulatory control functions.

DEA is working to fulfill both the regulatory control and enforcement aspects of the Diversion Control Program in FY 2011 and beyond. This approach will help the Diversion Control Program meet immediate and future needs regarding both regulatory control and enforcement activities and ensure the appropriate mix of Diversion Investigators, Special Agents, and support personnel.

Justification

Regulatory Activities

DEA requests \$3,384,000 for 23 diversion investigator positions to address existing staffing shortfalls in the regulatory program and to increase the focus on regulatory oversight functions. This includes the modification of chemical and regulatory work plans to increase the frequency of scheduled investigations and to broaden the pool of registrants that are subject to scheduled regulatory investigations. Increasing the frequency of inspections/investigations will ultimately help industry comply with the Controlled Substances Act (CSA) and its implementing regulations, and more easily identify those who are potential avenues for diversion. The last significant increase to Diversion Investigator positions was accomplished in the FY 2004 budget;

however, 108 vacant Diversion Investigator positions were converted to Special Agent positions because of immediate law enforcement requirements identified in the 2006 OIG report. Thus, the loss of Diversion Investigator positions, combined with the need to step up an aggressive regulatory control program requires replenishment and an increase in Diversion Investigator resources. DEA's goal as described will be implemented over several years as positions are authorized, collections support funding requests, and positions are staffed.

In addition, the new work plan modification will require that all newly-approved controlled substance and chemical registrants will be subject to a scheduled investigation within one year of approval and issuance of a DEA registration. Thus, this will require the deployment of additional Diversion Investigators.

Enforcement Activities

DEA requests \$23,560,000 (including \$3,939,000 in non-personnel funding) and 97 positions (including 60 special agents and 37 diversion investigators) for Tactical Diversion Squads (TDSs). TDSs combine Special Agents, Diversion Investigators, and State and Local Task Force Officer (S&L) resources to provide law enforcement support to DEA's Diversion Control Program. DEA is currently using existing Special Agent and Diversion Investigator positions to organize TDSs in each domestic field division. DEA requests 60 new Special Agents and 37 new Diversion Investigator positions to solidify existing TDSs where S&L personnel are limited and to establish new TDSs in areas of significant pharmaceutical diversion; 3 new Telecommunications Specialist (ITS) positions to support the Office of Investigative Technology's Diversion Internet Intercept Program; and 5 new Attorney positions to support case development including Orders to Show Cause and Immediate Suspensions. This request also includes \$3,175,000 for overtime and other overhead costs for 64 new State and local Task Force Officers (TFO), and \$264,000 for 8 new contract clerical personnel for TDSs.

TDSs allow for the unification of separate and sometimes disparate Federal, State, and local information, authorities, and enforcement programs. They work with S&L law enforcement authorities in developing more effective enforcement programs against diversion. TDSs also help coordinate with various judicial districts to maximize the effectiveness of multiple investigations and prosecutions of those involved in the diversion of controlled substances and chemicals.

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