

Subject

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

Date

JAN 0 4 2011

То

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

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

On December 20, 2010, this section received your e-mail requesting a review of three (3) quota applications from two registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Mylan Chestnut Ridge Road, West Virginia (10920)

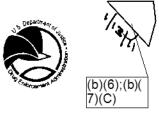
QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

(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 $\binom{(b)(6);(b)(7)(0)}{C}$ or SC $\binom{(b)(6);(b)(7)(C)}{C}$



Subject

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

JAN 1 3 2011

То

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

From Boochty Left achand Barbara J. Bood

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

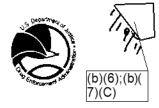
Abbott Laboratories North Chicago (IPQ02 Mylan Pharmaceuticals, Inc. (IPQ025) Hisamitsu California Laboratories (IPQ148 USP (10906) Mylan (10905) Almac (10908) Cerilliant (10909) Mylan (10913) Mylan (10914) DSM Pharmaceuticals (10948) Mylan Pharmaceuticals (10949) Mylan Pharmaceuticals (10950) 3M Drug 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)

29)	(b)(4);(b)(7)(E)
8)	

(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 - Hauppage (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

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 p	ertaining to this information, please feel	free to contact me $\binom{D}{(0)}$ for SC
(b)(6);(b)(7)(C)		



Subject	Date
Quota Letters Received as of January 13, 2011 (DFN: 630-08.2)	JAN 1 8 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diverison 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)

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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 $\binom{(b)(6);(b)(7)(C)}{C}$ or SC



Subject	Date
Quota Letters Received as of January 19, 2011 (DFN: 630-08.2)	JAN 2 1 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diversion Control	From Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

On January 19, 2011, this section received your e-mail requesting a review of seventeen (17) quota applications from fifteen (15) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

	(b)(4);(b)(7)(E)	
Pii (11016)		
Pii (11017)		
Pii (11018)		
Qualitest Pharmaceuticals (11019)		
Metrics (11020)		
Mallinckrodt (11021)		
Neos Therapeutics, LP (11023)		
AMRI Rensselear, Inc. (11024)		
AMRI Rensselear, Inc. (11025)		
KV Pharmaceuticals (11026)		
KV Pharmaceuticals (11026) 2 of 2		
King Pharmaceuticals (11036)		
Catalent Pharma Solutions (11037)		
Noramco (11038)		
Penick (11039)		
Glatt Air (11040)		

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

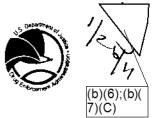
Currently under OSC

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 $\binom{(b)(6);(b)(7)}{C}$ or SC $\binom{(b)(6);(b)(7)}{C}$

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Subject	Date
Quota Letters Received as of January 24, 2011 (DFN: 630-08.2)	JAN 2 5 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diverison Control	From Jones Well 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 (11047) Penick (11051) Siegfried (11052) 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 $\binom{(b)(6);(b)(7)()}{C}$ or SC $\binom{(b)(6);(b)(7)(C)}{C}$



Subject Additional Quota Requests as of January 25, 2010 (DFN: 630-08.2)	Date
	JAN 2 7 2010
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diversion Control	From A A A A A A A A A A A A A A A A A A A

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)	(b)(4);(b)(7)(E)
Elsohyl Laboratorics (9621)	
Norameo (9625)	
Micron Technologies, Inc. (9626)	
Safecor (9627)	
Austin Pharma (9628)	
Sigma-Aldrich (9629)	
Eminenet (9634)	
Siegfried (9635)	
Siegfried (9636)	
Siegfried (9637)	
Watson (9638)	
Watson (9639)	
AAIPharma (9640)	

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.

<u>1) you have any questions pertaining to this information, please feel free to contact me (b)(6);(b)(7)</u> or SC (C)



Subject	Date
Quota Letters Received as of January 28, 2011 (DFN: 630-08.2)	JAN 3 1 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diverison 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	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 $\binom{(b)(6);(b)(7)(C)}{(b)(6);(b)(7)(C)}$ or SC.



Subject Quota Letters Received as of January 31, 2011 (DFN: 630-08.2)	Date
	FEB 0 2 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section	From mee und M Barbara J. Boockholdt, Chief Regulatory Section
Office of Diverison Control	Office of Diversion Control
On January 31, 2011, this section received your e-ma applications from twelve (12) registered manufacture administrative/legal actions against these applicants	ers to determine if there are any pending

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)

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

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



Subject (b)(4);(b)(7)(E)	Date
2011 Procurement Quota Increase Request Hydrocodone (DFN:630-08.2)	FEB 0 3 2011
To Christine A. Sannerud, Ph.D, Chief Drug & Chemical Evaluation Section Office of Diversion Control	From Barbaia 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 ar	d CSA reviews of approximately one hundred fifty-three (153) of ^{(b)(4)}	
ODGK conducted NADIDIS a		
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	s pertaining to this information, please feel free to contact $\operatorname{me}_{(C)}^{(b)(6);(b)(7)()}$ or S	SC
(b)(6);(b)(7)(C)		



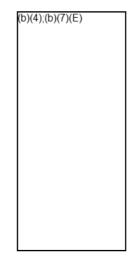
Subject Quota Letters Received as of February 3, 2011	Date
(DFN: 630-08.2)	FEB 0 3 2011
То	From A
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control

On February 3, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from ten (10) registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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



QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

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

Currently Under Review/Investigation

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

If you have any questions pertaining to this information, please feel free to contact $me_{(b)(6);(b)(7)(C)}^{(b)(6);(b)(7)(C)}$ or SC



SubjectDateQuota Letters Received as of February 10, 2011
(DFN: 630-08.2)FEB 14 2011

То

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

From Barlian Beockholdt

Barbara J. Boockholdt, 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)	(b)(4);(b)(7)(E)
Johnson Matthey (11100)	
Cephalon, Inc. (11101)	
Siegfried (11102)	
Mylan Chestnut Ridge Road, West Virginia (11103)	
Upsher-Smith (11104)	
PrePak Systems (11105)	
Impax Pennsylvania (11106)	
Impax Pennsylvania (11106)(2 of 2)	
Watson (11107)	
Watson (11107)(2 of 2)	
Nexgen Pharma, Inc. (11108)	
University of Mississippi (11109)	
Bilcare (11111)	
Patheon (11112)	
Patheon (11113)	
Elan Holdings (11114)	
Epic Pharma (11115)	
Actavis South-Atlantic (11116)	
Cambrex (11117)	

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

(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 $\binom{(b)(6);(b)(7)(}{C)}$ or SC $\binom{(b)(6);(b)(7)(C)}{C}$



Subject Quota Letters Received as of February 15, 2011 (DFN: 630-08.2)	Date FEB 1 6 2011
To	From
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	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.

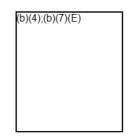
QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

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

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

If you have any questions	pertaining to this information, please feel free to contact me $\frac{(b)(c)}{C)}$	^{(6);(b)(7)(} or SC
(b)(6);(b)(7)(C)		



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Subject Quota Letters Received as of February 17. 2011	Date
(DFN: 630-08.2)	FEB 2 3 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diverison Control	From Mus Control From Mus Control For Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control
On February 17, 2011, this section received your e	\checkmark

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

Parr Laboratorios (11154)	(b)(4);(b)(7)(E)
Barr Laboratories (11154)	
Norwich Pharmaceuticals (11155)	
Pharmedium (11156)	
Pharmedium (11157)	
Qualitest Pharmaceuticals (11158)	
Catalent Pharma Solutions (11159)	
PD-RX Pharmaceuticals (11160)	
Alltech Associates (11163)	
Aurolife Pharma LLC (11164)	
Fisher Clinical Services (11165)	
Johnson Matthey (11166)	
Fisher Clinical Services (11170)	
Gallipot (11171)	
Abbott Laboratories North Chicago (11172)	
Tedor Pharma Inc (11173)	

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

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



Subject	Date
Quota Request as February 25, 2011 (DFN: 630-08.2)	March 4, 2011
То	From America Unit Barbara J. Boockholdt, Chief
Christine A. Sannerud, Ph.D., Chief	Regulatory Section
Drug & Chemical Evaluation Section Office of Diversion Control	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	(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)

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: ChristineASanqerud, PhD/Chief/ODE/Drug&ChemicalEvaluationSection

Ce: ODG (b)(6);(b)(7)(C) 3/4/2011:ReqDoc2/25/2011 Cc: ODGI

From: Sent: To: Subject:	(b)(6);(b)(7)(C) <u>Friday, February 25,</u> 2011 3:39 PM (b)(6);(b)(7)(C) RE: Quota Letters Received as of February 25, 2011
(b)(6);(b)(7)(C) The correct reg (b)(6);(b)(7)(C)	istration number for Qualitest (AKA Vintage) is ^{(b)(4);(b)(7)(E)}
	oruary 25, 2011 3:09 PM) Boockholdt, Barbara J.;(b)(6);(b)(7)(C) iota Letters Received as of February 25, 2011
11175	Qualitest
Hello (b)(6);(b)(7)(C	Qualitest
Hello(b)(6);(b)(7)(C The above name	Qualitest

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) Please see attached quota reviews. will be away for another week or two.	
Thanks! (b)(6);(b)(7)(C) $(c) = C = C + C + C + C + C + C + C + C + C$	
Chief, Regulatory Unit/ODGR DEA Headquarters (b)(6);(b)(7)(C) (Office) (Fax) (Blackberry)	
(b)(6);(b)(7)(C) <u><u>a</u><u>usdoj.gov</u></u>	C 1

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From: (b)(6);(b)(7)(C)]		
Cast, Friday, February	25, <u>2011 10:04 AM</u>	(b)(6);(b)(7)(C)	
To: Boockholdt, Barbara	(b)(b)(c)(c)(7)(c)	11] Hill, Robert L.
Cc: Sannerud, Christine	A. $(b)(b)(c)(c)(c)$],
Subject: Quota Letters	Received as of repr	uary 20, 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	(b)(4);(b)(7)(E)
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)(6);(b)(7)(C)

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Program Analyst Quota Unit (ODEQ) Drug & Chemical Evaluation Section Office of Diversion Control [(b)(6);(b)(7)(C)



Subject	Date
Quota Request as February 28, 2011 (DFN: 630-08.2)	MAR 0 4 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diversion Control	From Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

On February 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.

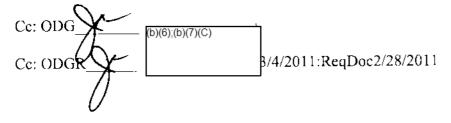
ODGR conducted reviews (NADDIS, CSA, etc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

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



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(b)(6);(b)(7)(C)	7
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) <u>Tuesdav. March 01. 20</u> 11 7:51 AM (b)(6);(b)(7)(C) <u>Boockholdt, Barbara J.;(b)(6);(b)(7)(C)</u> FW: Quota Letters Received as of February 28, 2011
(b)(6);(b)(7)(C) See attached quota re	equest.
Thanks! (b)(6);(b)(7)(C) Chief, Regulatory Un DEA Headquarters (b)(6);(b)(7)(C) (Offic (Fax)	

CONFIDENTIALITY NOTICE: This communication, with its contents, may contain privacy, confidential, and/or legally privileged information. It is solely for the use of the intended recipient(s). Unauthorized interception, review, use, and/or disclosure is prohibited and may violate applicable laws including the Electronic Communications Privacy Act. If you are not the intended recipient, please contact the sender and destroy all copies of the communication.

From: ^{(b)(6);(b)(7)(C)}				
Sent: Monday, February 2	8, 2011 5:04 PM			
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 Re	ceived as of Febru	iary 28, 2011		

Good Afternoon,

(Blackberry)

ausdoj.gov

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

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

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

Thank you in advance.

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	

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

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



Subject	Date
Quota Letters Received as of March 3, 2011	
(DFN: 630-08.2)	MAR 0 9 2011

То

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

Barbara J. Boackholdt, Chief From

Regulatory Section Office of Diversion Control

On March 3, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

(11015)	(b)(4);(b)(7)(E)
Halo Pharmaceutical Company (11215)	
Norac Inc (11216)	
Axcentra (11220)	
Ortho McNeil Pharmaceutical (11221)	
Hospira, Inc. NC (11222)	
Impax Pennsylvania (11223)	
Archimica (11225)	
Anderson Packaging, Inc (11226)	
Aurolife Pharma (11227)	
Coating Place Inc (11228)	
Cerilliant (11229)	
Watson (11230)	
Cody Labs (11231)	

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

If you have any questions pertaining to this information, please feel free to contact $me_{C)}^{(b)(6);(b)(7)(C)}$ or SC



SubjectDateQuota Letters Received as of March 7, 2011MAR 0 9 2011(DFN: 630-08.2)MAR 0 9 2011

Тσ

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

From Barbar Deochto lat

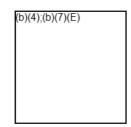
Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

On March 7, 2011, this section received your e-mail requesting a review of five (05) quota applications to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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



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

If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)()}$ or SC (b)(6);(b)(7)(C)



Subject	Date	
Quota Letters Received as of March 11, 2011 (DFN: 630-08.2)	MAR 1 4 2011	
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diverison Control	From Marken Marken Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control	
On March 11, 2011, this section received your e-mail requesting a review of thirteen (13) quota applications from twelve (12) registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.		
ODGR conducted reviews (NADDIS, CSA, etc), as input and recommendations. Provided below are the	well as surveyed the responsible field offices for their results and recommendations.	
	OF OF REPOCATORY INFORMATION	

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Barr Laboratories (11241) Mylan Chestnut Ridge Road, West Virginia (11242) Fisher Clinical Services (11244) Glatt Air (11245) Cima Brooklyn Park (11246) Par Pharmaceutical (11247) (1 of 2) Par Pharmaceutical (11247) (2 0f 2) Reckitt Benckiser (11248) Lannett (11249) Lannett (11249) (2 of 2) Norwich Pharmaceuticals (11250) Barr Laboratories (11251) Bryant Ranch Prepack (11253)

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

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



Subject	Date
Quota Letters Received as of March 18, 2011 (DFN: 630-08.2)	MAR 2 5 2011

То

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

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

On March 18, 2011, this section received your e-mail requesting a review of thirty-seven (37) quota applications from thirty-four (34) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

	(b)(4);(b)(7)(E)
Barr Labs (11260)	
Purdue (11261)	
Janssen Puerto Rico (11262)	
Watson Labs (11263)	
Alliance Contract Pharma (11264)	
Novel Laboratories (11266)	
Novel Laboratories (11267)	
Pharmedium Cleveland (11268)	
Pharmedium Cleveland (11270)	
Safecor Health, LLC (11271)	
Pisgah Labs Inc (11273)	
Abbott Laboratories North Chicago (11274)	
Cody Labs (11275)	
Cima Brooklyn Park (11276)	
AmeriSource Ohio (11277)	
Cedarburg (11279)	
Acura Pharmaceutical Technologies (11280)	
Biochemical Diagnostics (11282)	
Catalent Pharma Solutions (11283)	
Catalent Pharma Solutions (11284)	

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	(b)(4);(b)(7)(E)
Patheon (11285)	
Vintage Pharmaceuticals (11286)	
Vintage Pharmaceuticals (11287)	
Vintage Pharmaceuticals (11288)	
Halo Pharmaceutical Company (11389) 112.89	
Pharmaceutics Intl Inc (11290)	
Pharmaceutics Intl Inc (11290) (2 of 2)	
Alvogen (11291)	
Alvogen (11292)	
Alvogen (11293)	
DSM (11294)	
Wildlife (11297)	
Sun Pharmaceutical Industries (11298)	
Cima Brooklyn Park (N296)	
Cayman Chemical (11300)	
Alaunus Pharmaceutical, Inc. (11301)	
Mallinckdrodt St. Louis (11302)	

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

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	pertaining to this information, please feel free to contact me $\binom{(b)(6),(b)(7)}{C}$ or SC
If you have any questions	pertaining to this information, please feel neer to the termine of
If you have any queene	-
(b)(6);(b)(7)(C)	



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Subject	Date
Quota Request as March 24, 2011 (DFN: 630-08.2)	
	MAR 2 8 2011
То	From gracelud
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diversion Control	Office of Diversion Control

On March 24, 2011, this section received your e-mail requesting a review of fifteen (15) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

(b)(4);(b)(7)(E)	
(D)(4),(D)(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 $^{(b)(6);(b)(7)(C)}$

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Subject	Date
Quota Letters Received as of March 28, 2011 (DFN: 630-08.2)	MAR 2 9 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diverison Control	From Wes Ull Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

On March 28, 2011, this section received your e-mail requesting a review of seven (07) quota applications with six (6) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

(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 $\binom{(b)(6);(b)(7)(C)}{C}$ or SC



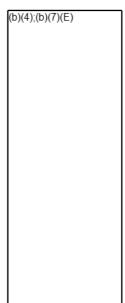
Subject	Date
Quota Request as April 1, 2011 (DFN: 630-08.2)	APR 0 6 2011
То	From ALL A Barbara J. Boockholdt, Chief
Christine A. Sannerud, Ph.D., Chief	
Drug & Chemical Evaluation Section Office of Diversion Control	Regulatory Section Office of Diversion Control

On April 1, 2011, this section received your e-mail requesting a review of fifteen (15) quota applications with thirteen (13) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

UCB Manufacturing (11338) Vintage Pharmaceuticals (11339) Norac (11340) Medisca (11341) AAI Pharma 1726 N. 23rd St (11342) Norwich Pharmaceuticals (11343) AmeriSource Ohio (11344) Cambrex (11347) 3M 3M Center (11348) Boehringer Ingelheim (11350) Neos Therapeutics, LP (11351) Akorn (11352) Bienheim Pharmacal (11353) Bienheim Pharmacal (11354) Neos Therapeutics, LP (11355)



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

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



Subject	Date
Quota Letters Received as of April 7, 2011 (DFN: 630-08.2)	APR 1 1 2011
То	From Mars Und Barbara J. Boockholdt, Chief
Christine A. Sannerud, Ph.D., Chief	
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control

On April 7, 2011, this section received your e-mail requesting a review of nine (09) quota applications with eight (08) registered manufactures to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

(b)(4);(b)(7)(E)	
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1	
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Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions	pertaining to this information	ı, please feel	free to co	ntact me ^{(b)(6);(b)(7} _{C)})(or SC
(b)(6);(b)(7)(C)					



SubjectDateQuota Letters Received as of April 18, 2011
(DFN: 630-08.2)Date

То

Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diversion Control From Barhune Boockholdt Barbara J. Boockholdt, Chief Regulatory Section

Office of Diversion Control

On April 18, 2011, this section received your e-mail requesting a review of thirty-three (33) quota applications from twenty-five (25) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

	(b)(4);(b)(7)(E)
Mallinckrodt St. Louis (11375)	
Mallinekrodt St. Louis (11376)	
Mallinckrodt St. Louis (11414)	
Mikart Marietta Boulevard (11391)	
Arista (11365)	
Baxter (11406)	
Catalent Pharma Solutions (11409)	
Archimica (11403)	
Central Admixture - San Diego (11396)	
Elan Holdings (11410)	
Elan Holdings (11413)	
Sandoz (Geneva Pharmaceuticals, Inc) (11404)	
Almac Clinical Services (11416)	
Halo Pharmaceutical Company (11401)	
Halo Pharmaceutical Company (11401) 2 of 2	
Halo Pharmaceutical Company (11415)	
Johnson Matthey (11367)	
Janssen Puerto Rico (11407)	
KVK Tech, Inc. (11374)	
Mylan Technologies (11369)	

Metrics (11368)	
Purdue (11405)	
Aphena Pharma (11373)	
Cambrex (11417)	
Sandoz (Geneva Pharmaceuticals, Inc) (11402)	
Tris Pharma, Inc (11364)	
Vintage Pharmaceuticals (11408)	
Watson (11392)	
Watson (11393)	
Watson (11394)	
Watson (11393) 2 of 2	
Watson (11395)	

QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

(b)(4)

Currently Under Investigation

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

If vou have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)(C)}$ or SC

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

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



Subject

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

APR 2 8 2011

То

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

From Barbara J. Booch o LAP

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

On April 26, 2011, this section received your e-mail requesting a review of twenty-nine (29) quota applications from twenty (20) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

Catalent Pharma Solutions (11427) Vintage Pharmaceuticals (11428) Ameridose, LLC (11429) Penick (11430) Mylan Chestnut Ridge Road, West Virginia (11431) DSM (11432) Jerome Stevens (11433) Hospira, Inc. (11434) Amneal - Hauppage (11435) AMRI Rensselear, Inc. (11436) Sun Pharmaceuticals (11437) Mallinckrodt St. Louis (11439) Mallinckrodt St. Louis (11440) Mallinckrodt St. Louis (11441) Mallinckrodt St. Louis (11442) Unit Dose Solutions (11444)	(b)(4);(b)(7)(E)
Unit Dose Solutions (11443)	

Unit Dose Solutions (11448) Unit Dose Solutions (11449) Barr Laboratories (11450) Stat Rx (11451) Allergy Laboratories (11452) Mylan Chestnut Ridge Road, West Virginia (11454) Johnson Matthey (11455) AnazaoHealth (11457) Fisher Clinical Services (11458)

(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 pe	ertaining to this information, please f	eel free to	contact me	(b)(6);(b)(7) (C)	or SC
(b)(6);(b)(7)(C)					



Subject (b)(4) (DEA # ^{(b)(4);(b)(7)(E)} 2011 Procurement Quota Increase Request Oxycodone (for sale) (DFN: 630-08.2)	Date MAY 0 5 2011	
To	Barbara J. Boockholdt, Chief	
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief	
Drug & Chemical Evaluation Section	Regulatory Section	
Office of Diverison Control	Office of Diversion Control	

On March 2, 2011, this section received your memorandum requesting a review of a quota increase submitted by (b)(4) is requesting a 2011 procurement quota increase from 2.0 to 9.5kg of oxycodone, an increase of 7.5kg. According to (b)(4) increase in sales. (b)(4);(b)(7)(E)

(b)(4) provided year to date sales for 2011. The names of the registrants were run through NADDIS to determine if there were any ongoing field investigations. The DEA registration numbers were also run through RICS to determine if the registrations were current. Provided below are the results and recommendations.

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



 Subject
 Date

 Quota Letters Received as of May 2, 2011
 Image: Comparison of May 2, 2011

 (DFN: 630-08.2)
 Image: Comparison of May 2, 2011

То

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

From Barbara J. Boockholdt, Chief

Regulatory Section Office of Diversion Control

On May 3, 2011, this section received your e-mail requesting a review of forty-two (42) quota applications from thirty-one (31) registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

	(b)(4);(b)(7)(E)
Fisher Clinical Services (11460)	
Noramco Delaware (11461)	
Noramco Delaware (11462)	
Noramco Delaware (11463)	
Epic Pharma (11464)	
Letco Medical (11465)	
Legacy Pharmaceutical Packaging (11466)	
Legacy Pharmaceutical Packaging (11467)	
KP Pharmaceutical Tech, Inc. (11470)	
Siegfried (11471)	
Siegfried (11472)	
Siegfried (11473)	
Agilent Technologies (11474)	
Alvogen (11475)	
Norwich (11477)	
KVK Tech, Inc. (11479)	
Sigma Aldrich (11481)	
Mylan Chestnut Ridge Road WVA (11482)	
Mylan Chestnut Ridge Road WVA (11483)	
Barr Labs (11484)	

Barr Labs (11485) DSM (11486) Advanced Pharma (11490) Noramco, Inc (11491) Noramco, Inc (11492) Cayman Chemical (11493) AMRI Rensselear, Inc (11495) Siemens Healthcare Diagnostics Inc. (11496) Coating Place Inc. (11502) Mallinckrodt (11503) Cerilliant (11504) Mylan Chestnut Ridge Road WVA (11505) Mylan Chestnut Ridge Road WVA (11506) Siegfried (11507) Mallinckrodt St. Louis (11508) Collegium Pharmaceutical (11509) 1of 2 Collegium Pharmaceutical (11509) 2of 2 Actavis South-Atlantic (11512) Bilcare Global Clinical Supplies (11513) Archimica (11514) Siegfried (11515) Formurex, Inc. (11516)

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 $me_{C}^{(b)(6);(b)(7)(c)}$ or PA

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



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Subject	Date
Quota Letters Received as of May 5, 2011 (DFN: 630-08.2)	MAY 1 0 TOIL

То

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

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

On May 5, 2011, this section received your e-mail requesting a review of eight (08) quota applications from manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Physicians Total Care (11517) Watson Pharmaceuticals (11518) Catalent Pharma Solutions (11519) Safecore Health, LLC (11520) KVK Tech, Inc. (11521) Mylan Pharmaceuticals (11522) Coating Place, Inc. (11523) Hisamitsu California Laboratories (11524) (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 per	taining to this information, please feel free to co	ontact me $\binom{(b)(6);(b)(7)}{C}$ or PA
(b)(6);(b)(7)(C)		



Subject

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

MAY 3 1 2011

Christine

То

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

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

Date

On May 17, 2011, this section received your e-mail requesting a review of nine (09) quota applications with seven (07) registered manufactures 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, ctc), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Alliance Contract Pharma (11531) Neogen Corp (11533) Cambrex (11534) Cambrex (11535) AmeriSource Ohio (11536) AmeriSource Ohio (11537) Johnson Matthey (11538) Paddock (11539) (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	s pertaining to this information, please feel free to contact me	(b)(6);(b)(7)(C)	or SC
(b)(6);(b)(7)(C)		0)	1



Subject

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

JUN 0-3 2011

То

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

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

Date

On May 26, 2011, this section received your e-mail requesting a review of thirty-seven (37) quota applications from twenty-three (23) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

Actavis South-Atlantic (11552)	(b)(4);(b)(7)(E)
Amneal – Hauppage (11587)	
Aurolife Pharma (11577)	
Barr Laboratoriess (11553)	
Boehringer Ingelheim (11579)	
Boehringer Ingelheim (11575)	
CorePharma Wood Avc (11547)	
CorePharma Wood Ave (11546)	
CorePharma Wood Ave (11548)	
DSM (11581)	
Impax Pennsylvania (11578)	
Johnson Matthey (11567)	
Johnson Matthey (11563)	
Johnson Matthey (11565)	
Johnson Matthey (11568)	
Johnson Matthey (11569)	
Johnson Matthey (11570)	
Johnson Matthey (11564)	
Johnson Matthey (11571)	

(b)(4);(b)(7)(E) Mallinckrodt St. Louis (11583) Mallinckrodt St. Louis (11582) Mallinckrodt St. Louis (11558) Mallinckrodt St. Louis (11584) Medisca (11599) Mylan Chestnut Ridge Road, West Virginia (11560) Noramco (11588) Noramco Delaware (11562) Noramco Delaware (11561) Novartis Consumer Health Lincoln (11585) Patheon (11550) Purduc (11586) Rhodes (11580) Sandoz (formerly Geneva Pharmaceuticals (11557) Specialty Compounding (11556) Vintage Pharmaceuticals (11549) Vintage Pharmaceuticals (11589)

QUOTA APPLICANTS 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.

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If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)(C)}$ or SC



Subject	Date
(b)(4) (DEA $\#^{(b)(4);(b)(7)(E)}$	
2011 Procurement Quota Increase Request	
Hydrocodone	HINLA 0 2011
(DFN:630-08.2)	JUN 0 9 2011

То

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

From Barbara J. Boochholdt, Chief

Regulatory Section Office of Diversion Control

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

ODGR conducted NAD	DIS and CSA re	views of approximately ninety-seven	(97) of	(b)(4)
customers as well as on	(b)(4)		` '	

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

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

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 $\binom{(b)(6);(b)(7)}{(c)}$ or S	SC
(b)(6);(b)(7)(C)		



Subject Quota Letters Received as of June 9, 2011 (DFN: 630-08.2)	Date JUN 1 5 2011	
To Christine A. Sannerud, Ph.D., Chief	From San Lan Dooch a Lolt Barbara J. Boockholdt, Chief	

Drug & Chemical Evaluation Section Office of Diversion Control Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

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

On June 9, 2011, this section received your c-mail requesting a review of twenty-six (26) quota applications from twenty-three (23) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

High miters California Laboration (11001)
Hisamitsu California Laboratories (11281)
Halo Pharmaceutical Company (11592)
Patheon (11593)
Noramco Delaware (11594)
Amneal - Hauppage (115965)
Alza Vacaville (11597)
Novel Laboratories (11598)
Cerilliant (11600)
Watson (11602)
B&B Pharmaceuticals (11604)
Kremers Urban Pharma (11605)
Watson Pharma (11607)
Elan Holdings (11608)
Almac Clinical Services (11610)
Alza Vacaville (11611)
Alza Vacaville (11612)
Siegfried (11613)
Mallinckrodt St. Louis (11614)
Catalent Pharma Solutions (11615)
Halo Pharmaceutical Company (11616)
•

Pharm-RX (11617)
B&B Pharmaceuticals (11618)
AmeriSource Ohio (11619)
Anderson Packaging, Inc. (11620)
Sandoz (formerly Geneva Pharm, Inc) (11621)

(b)(4);(b)(7)(8	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)	



Subject Quota Letters Received as of June 23, 2011

(DFN: 630-08.2)

Date

JUL 0 1 2011

То

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

From Booch . Ut Barbara J. Boookholdt, Chief Regulatory Section

Office of Diversion Control

On June 23, 2011, this section received your e-mail requesting a review of nineteen (19) quota applications from eighteen (18) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

	(b)(4);(b)(7)(E)
Johnson Matthey (11456)	
Watson Pharma (11603)	
Norac (11622)	
Banner California (11623)	
Hisamitsu California Laboratories (11624)	
Alza Vacaville (11625)	
Alza Vacaville (11626)	
Catalent Pharma Solutions (11627)	
Mirror Pharmaceuticals (11628)	
Bilcare Global Clinical Supplies (11630)	
Pharmaceutical Associates (11631)	
Endo Pharmaceuticals (11634)	
Mallinckrodt St. Louis (11637)	
VistaPharm (11638)	
Alvogen (11639)	
Novartis Consumer Health Lincoln (11640)	
Hospira, Inc. NC (11646)	
Mikart Marietta Boulevard (11647)	
Mikart Marietta Boulevard (11647) 2 of 2	
· · · · ·	

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

If you have any questions pertaining to this information, please feel free to contact $me_{C)}^{(b)(6);(b)(7)(C)}$ or SC



Subject

Quota Letters Received as of July 1, 2011 (DFN: 630-08.2) Date

JUL 1 2 2011

То

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

From Balan Boochholdt Barbara J. Boockholdt, Chief

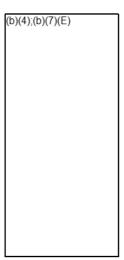
Regulatory Section Office of Diversion Control

On July 01, 2011, this section received your e-mail requesting a review of twelve (12) quota applications from seven (07) registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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



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

If you have any questions pertaining to this information, please feel free to contact $me_{(C)}^{(b)(6);(b)(7)(C)}$ pr SC



Subject

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

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

То

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

From Lan Beackholdt

JUL 1'2 2011

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

Date

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

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

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

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

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

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

If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)()}$ or SC



Subject

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

JUL 2 1 2011

Тο

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 14, 2011, this section received your e-mail requesting a review of thirty (30) quota applications from twenty-seven (27) registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise 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.

	(b)(4);(b)(7)(E)
Anesta (11676)	
Teva Pharmaceuticals (11677)	
AAI Pharma 1726 N. 23 rd St (11679)	
Vintage Pharmaceuticals (11680)	
Vintage Pharmaceuticals (11681)	
Catalent Pharma Solutions (11683)	
Norwich Pharmaceuticals (11684)	
B & B (11685)	
Fisher - Bristol, PA (11686)	
Clinical Supplies Mgmt (11687)	
Barr New Jersey (11688)	
Janssen Puerto Rico (11689)	
Core Rx (11690)	
Durect (11692)	
Formurex (11693)	
Elite (11694)	
Hospira, Inc. NC (11698)	
Watson Connecticut (11699)	
Cerilliant (11700)	
CorePharma Wood Ave (11701)	

	(b)(4);(b)(7)(E)
Patheon (11702)	
King Pharmaceuticals (11703)	
Impax Pennsylvania (11704)	
CAPS (11705)	
Watson Connecticut (11707)	
UCB Manufacturing (formerly Celltech NY) (11708)	
UCB Manufacturing (formerly Celltech NY) (11709)	
Dispensing Solutions, Inc. (11712)	
Novartis Consumer Health Lincoln (11713)	

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	s pertaining to this information, please feel free to contact me	b)(6);(b)(7)(C)	or SC
(b)(6);(b)(7)(C)	L .		i



Subject

أسالها

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

Date

JUL 2 1 2011

То

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

From ular Boochholdt Barbara J. Boogkholdt, Chief

Regulatory Section Office of Diversion Control

On July 19, 2011, this section received your e-mail requesting a review of sixteen (16) quota applications from registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Medisca (11559) Upsher-Smith (11714) Upsher-Smith (11715) Par (11716-1) Par (11716-2) Patheon (11717) Purdue (11718) **DPT Paco Way (11719)** Tris Pharma, Inc. (11720) UMISS (11721) Aurolife Pharma (11722) Impax Pennsylvania (11723) Sandoz (11724) Lannett (11725) Halo Pharmaceutical Company (11726) Epic Pharma (11727)

(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 $me_{C}^{(b)(6);(b)(7)()}$ or SC

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Subject

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

Date

JUL 2 9 2011

То

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

From Barlen Bookholdt Barbara J. Bogckholdt, Chief

Regulatory Section Office of Diversion Control

On July 22, 2011, this section received your e-mail requesting a review of twenty-six (26) quota applications from twenty-three (23) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

Med-Pharmex (11200)	(b)(4);(b)(7)(E)
Fisher Clinical Serices (11728)	
Interchem Corp (11729)	
Restek (11730)	
PD-RX Pharmaceuticals (11731)	
Catalent Pharma Solutions (11732)	
Amneal – Hauppage (11733)	
Tris Pharma, Inc. (11734)	
Hisamitsu California Laboratories (11735)	
Epic Pharma (11736)	
Aptuit, Inc. (11737)	
Par Pharmaceuticals (11738)	
Siegfried (11739)	
Siegfried (11740)	
PD-RX Pharmaceuticals (11743)	
AmeriSource Ohio (11744)	
Nostrum Labs, Inc. (11745)	
Aptuit, Inc. (11746)	
UPM Pharmaceuticals (11747)	
Watson Pharmaceuticals (11748)	

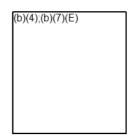
Metrics (11749) Janssen Puerto Rico (11750) Elan Holdings (11752) Aurolife Pharma (11753) Pisgah Labs (11754) Great Southern (11755)

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

If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)(C)}$ or SC



Subject

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

AUG 0 3 2011

То

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

Demiil > Silly 17 From Barbara J. Boockholdt, Chief

Regulatory Section Office of Diversion Control

Date

On July 29, 2011, this section received your e-mail requesting a review of twenty (20) quota applications from fifteen (15) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

Patheon (11757)	(b)(4);(b)(7)(E)
Johnson Matthey (11758)	
Johnson Matthey (11759)	
Johnson Matthey (11760)	
Johnson Matthey (11761)	
University of Mississippi (11762)	
ANI Pharmaceuticals, Inc. (11763)	
Cerilliant (11764)	
Chemtos (11765)	
Penick (11766) (1 of 2)	
Penick (11766) (2 of 2)	
Letco Medical (11766)	
Noramco Georgia (11769)	
Norac (11770)	
Watson Pharmaceuticals (11771)	
HiTech (11772)	
Penick (11773) (1 of 2)	
Penick (11773) (2 of 2)	
Metrics (11774)	
AustarPharma (11775)	

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

If you have any questions pertaining to this information, please feel free to contact me $\begin{bmatrix} (b)(6);(b)(7)(C) \\ C \end{bmatrix}$ or SC



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

Date

AUG 0 9 2011

То

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

From Boochhildt ß۵ Barbara J. Boockholdt, Chief **Regulatory Section** Office of Diversion Control

On August 4, 2011, this section received your e-mail requesting a review of fifteen (15) quota applications from fifteen (15) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Archimica (11777) Tris Pharma, Inc. (11778) Anderson Packaging, Inc. (11779) Paddock (11781) Noramco (11781) Fleming and Co. (11785) Watson Pharmaceuticals (11786) Mallinckrodt St. Louis (11787) Cambrex (11788) Microgenics (11789) Amneal – Hauppage (11790) Fisher Clinical (11791) Catalent Pharma Solutions (11792) Hospira, Inc. NC (11793) DSM (11794) (b)(4);(b)(7)(E)

QUOTA APPLICANT WITH ADVERSE OR DEROGATORY INFORMATION

(b)(4)

Under Investigation/Discussion Ongoing

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

If you have any questions pertaining to this information, please feel free to contact $mc_{(D)(6);(D)(7)(C)}^{(b)(6);(b)(7)(C)}$ or PA



Subject

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

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

AUG 1 1 2011.

То

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

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

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

ODGR conducted NADDIS and CSA reviews of approximately one hundred and seventy-nine (179) of (b)(4) customers as well as on (b)(4)

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

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

Currently Under Review/Investigation Retired Retired Retired Currently Under Suspension 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 $me_{C)}^{(b)(6);(b)(7)(C)}$ or SC



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

AUG 2 2 2011.

То

Subject

Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diversion Control From Barbara J. Bogekholdt, Chief Regulatory Section Office of Diversion Control

Date

On August 17, 2011, this section received your e-mail requesting a review of seventeen (17) quota applications from registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis Elizabeth LLC (109037) (b)(4);(b)(7)(E) Alza Corporation (109028) Ameridose, LLC (109030) Ameridose, LLC (109063) Amneal Pharmaceuticals of NY, LLC (109141) Cody Laboratories, Inc. (109075) Hospira Inc (109099) Janssen Cilag Manufacturing LLC (109098) Mallinckrodt Inc (109119) Mallinckrodt LLC (109072) Micron Technologies (109060) Neos Therapeutics, LP (109033) Noramco (109130) Ohm Laboratories (109034) Purdue Pharmaceuticals LP (109086) Sharp Corporation (109031) West-Ward Pharmaceuticals Corp (109113)

QUOTA APPLICANTS WITH ADVERSE OR DERGOATORY INFORMATION

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

Per consultation with the field offices, DEA docs 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.

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If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)(C)}$ or SC



Subject

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

Date

AUG 2 2 2011

То

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

From **Regulatory Section** Office of Diversion Control

On August 17, 2011, this section received your e-mail requesting a review of twenty-one (21) quota applications from eighteen (18) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

ODGR conducted reviews (NADDIS, CSA, ctc), 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

(b)(4);(b)(7)(E) AmeriSource Ohio (11795) ECI Pharmaceuticals (11796) Tris Pharma, Inc (11797) Noramco (11798) Watson Pharmaceuticals (11799) Watson Pharmaceuticals (11800) Watson Pharmaceuticals (11801) DSM (11802) Safecor Health, LLC (Regional Service Center (11803) Nexgen Pharma, Inc (11804) Cerilliant (11805) PD-RX Pharmaceuticals (11807) Advanced Pharma (11808) Advanced Pharma (11809) OHM Labs (11810) Elan Holdings (11811) Cambrex (11814) Cambrex (11815) Bio Pharm (11816) Norac (11770)

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

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

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



Subject	Date
Quota Letters Received as of August 22, 2011 (DFN: 630-08.2)	SEP 0 6 2011
То	From 1 C A like 11
Christine A. Sannerud, Ph.D., Chief	Barbara J. Bookholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control
	nail requesting a review of five (05) quota applications ere any pending administrative/legal actions against

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

(b)(4)	;(b)(7)(E))	٦

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 $me_{C)}^{(b)(6);(b)(7)(C)}$ or SC



Subject	Date
Quota Letters Received as of August 26, 2011 (DFN: 630-08.2)	SEP 0 6 2044
То	From Barbari Boockho Left Barbara J. Boockholdt, Chief
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control
On August 26, 2011, this section received your e-mail re of registered manufactures to determine if there were any these applicants and to advise ODE of the findings.	
ODGR conducted reviews (NADDIS, CSA, etc), as well input and recommendations. Provided below are the reso	• •

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

(b)(4);(b)(7)(E)	
1	

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 per	taining to this information, please feel free to contact me $\frac{(b)(6);(b)(7)}{(b)}$	or SC
(b)(6);(b)(7)(C)	0)	I

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Subject	Date
Quota Letters Received as of September 2, 2011 (DFN: 630-08.2)	
	SEP 0 8 2011
Drug & Chemical Evaluation Section Regula Office of Diverison Control Office	a J. Boockholdt, Chief atory Section of Diversion Control
On September 6, 2011, this section received your e-mail requesting applications from sixteen (16) registered manufacturers to determ administrative/legal actions against these applicants and to advise	line if there are any pending
ODGR conducted reviews (NADDIS, CSA, etc), as well as surve input and recommendations. Provided below are the results and recommendations.	
QUOTA APPLICANTS WITH NO ADVERSE OR DEI	ROGATORY INFORMATION
	(b)(4);(b)(7)(E)
PD-RX Pharma, Inc. (11833)	
Norac (11834)	
Johnson Matthey (11835) Johnson Matthey (11836)	
Sandoz (11837)	
Patheon (11838)	
Metrics (11840)	
Metrics (11841)	
Vintage Pharmaceuticals (11843)	
Vintage Pharmaceuticals (11844)	
AMRI Rensselear, Inc. (11845)	
PharmaForm (11846)	

ANI Pharmaceuticals, Inc. (11847)

Pharmaceutics International (11851)

Johnson Matthey (11848)

Watson Pharma (11850)

Elan Holdings (11852)

Cerilliant (11849)

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 $\binom{(b)(6);(b)(7)(C)}{C}$ or SC



Subject (b)(4);(b)(7)(E) 2011 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	Date SEP 0 8 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evalutaion Section (ODQ) Office of Diversion Control	From Barbana J. Boochholdt, Chief Regulatory Section (ODG) Office of Diversion Control
On August 4, 2011, this section received your memorandu submitted by ^{(b)(4)} ODQ is requesting a review specifically, information on whether the applicant's custor subject of an order to show cause or immediate suspension ODGR conducted NADDIS and CSA reviews of approxim	v of $(b)^{(4)}$ customers list, mers are currently under investigation or are n order.
$\frac{(b)(4)}{(b)(4)}$ customers as well as an in-depth investigation of	

ODG has determined that $(b)^{(4)}$ request for a quota increase should be denied. Grounds for this action are based upon failure to provide effective control against diversion of the controlled substances they manufacture as required by Title 21 USC 824(a)(4).

If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)()}$ or SC



Subject

Freedom Pharmaceuticals ^{(b)(4);(b)(7)(E)} 2011 Procurement Quota Request Hydrocodonc and Oxycodone (DFN:630-08.2)

То

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

OCT 0 4 2011

From Barlian Boockh. Barbara J. Boockholdt, Chief **Regulatory Section**

Regulatory Section Office of Diversion Control

On September 20, 2011, this section received your memorandum requesting a review of Freedom Pharmaceuticals' customers list, specifically, information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order.

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

No derogatory information was found

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

If you have any question	ns pertaining to this information, please fell free to contact $me_{C}^{(b)(6)}$	((b)(7)() or SC
(b)(6);(b)(7)(C)		



Subject

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

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

OCT 0 4 2011.

То

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

Boockholdt arbard bara J. Boookholdt, Chi Regulatory Section (ODG) Office of Diversion Control

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

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

The below listed information was found $on^{(b)(4)}$ customers:

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

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

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

(b)(4);(b)(7)(E) Currently Under Review/Investig	ation
--	-------

(b)(4);(b)(7)(E) Currently Under Review/Investigation		
(b)(4);(b)(5);(b)(7)(E)		
(b)(4);(b)(7)(E) (b)(4);(b)(7)(E)		
(b)(4);(b)(7)(E)		
Currently Under Suspension (b)(4);(b)(7)(E)		
Currently Under Suspension (b)(4);(b)(7)(E)		
Based upon a review of $(b)(4)$ customers, ODG recommends that ODQ adjust the quota granted to this company. Two of $(b)(4)$ customers are currently under an Immediate Suspension Order $(b)(4)$ $(b)(4)$ and nine (9) customers are under Review/Investigation.		
Quota to $(b)(4)$ should be reduced by at least the total kilogram amounts sold by the company to the above listed $(b)(4)$ customers.		

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

\$



 Subject
 Date

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

 To
 OCT 0 5 2011

 To
 Subject Diversion Control

 Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evaluation Section Office of Diversion Control
 From Boockhoubt Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

 On September 19, 2011, this section received your e-mail requesting a review of eleven (11) quota

applications from ten (10) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

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

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

If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6);(b)(7)()}$ or PA



Subject Quota Letters Received as of September 26, 2011 (DFN: 630-08.2)	Date OCT 0 5 2011
To	From
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief

Orug & Chemical Evaluation Section Office of Diversion Control Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control

On September 26, 2011, this section received your e-mail requesting a review of thirty-four (34) quota applications from thirty-three (33) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODQ of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Actavis MidAtlantic LLC (109528) Amneal Pharma of New York LLC (109260) Archimica, Inc (109471) B&B Pharmaceuticals (109489) Bio-Pharm Inc (109258) Boehringer Ingelheim Chem Inc (109259) Capricorn Pharma Inc (109463) Cerilliant Corporation (109501) CorePharma, LLC (109517) DSM Pharmaceuticals, Inc. (109488) Epic Pharma LLC (109493) Glatt Air Techniques Inc. (109472) Mallinckrodt Inc (109487) Mylan Pharmaceuticals Inc (109366) Mylan Pharmaceuticals Inc (109263) Neos Therapeutics, LP (109184) Noramco Inc (109524) Norwich Pharmaceuticals Inc (100462)	(b)(4);(b)(7)(E)
Norwich Pharmaceuticals Inc (109462)	

Noven Pharmaceuticals, Inc (109499) Patheon Pharmaceuticals, Inc (109500) Purdue Pharmaceuticals LP (109195) Sharp Corporation (109264) Specialty Compounding LLC (109465) Stat RX USA LLC (109521) Tris Pharma Inc ((109520) Vista Pharm Inc (109490) Watson Laboratories Inc – Florida (109503) Watson Laboratories Inc – Florida (109505) Emerson Resources Inc (11865)	(b)(4);(b)(7)(E)	
Emerson Resources, Inc (11865) Thermofisher Scientific (11866)		
Nesher Pharmaceuticals LLC (11868-1) Nesher Pharmaceuticals LLC (11868-2)		
Please note that (b)(4);(b)(7)(E) currently under investigation. (b)(4);(b)(7)(E)	listed above is not the (b)(4)	

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 $\begin{bmatrix} (b)(6);(b)(7)\\ (C) \end{bmatrix}$ or SC

2



Subject

Mikart Inc. (DEA #^{(b)(4);(b)(7)(E)} 2011 Procurement Quota Increase Request Hydrocodone (DFN:630-08.2) Date

OCT 1 3 2011

То

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

From Borakho ldt Barbara J. Boo¢kholdt, Chief **Regulatory Section** Office of Diversion Control

On September 30, 2011, this section received your memorandum requesting a review of Mikart Inc's customers list, specifically, information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order.

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

No derogatory information was found

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

If you have any questions pertaining to this information, please fell free to contact me $\binom{(b)(6);(b)(7)(C)}{C}$ or SC



Subject (b)(4) (DEA (b)(4);(b)(7)(E) 2011 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	Date OCT 1 3 2011
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evalutaion Section (ODQ) Office of Diversion Control	From Barbara J. Boochholdt, Chief Regulatory Section (ODG) Office of Diversion Control
On September 30, 2011, this section received your n submitted by $(b)(4)$ ODQ is requesting a specifically, information on whether the applicant's subject of an order to show cause or immediate susp ODGR conducted NADDIS and CSA reviews of ap (b)(4) customers as well as an in-depth investiga	review of (b)(4) customer list, customers are currently under investigation or are ension order. proximately one hundred and thirty-six (136) of
The below listed information was found on (b)(4)	customers: Currently Under Review/Investigation
(b)(4);(b)(Currently Under Review/Investigation 7)(E)
(b)(4);(Currently Under Suspension
(b)(4);(b)(7)(E)	Currently Under Review/Investigation

(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(t	Currently Under Review/Investigation
(b)(4);(b)(7)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Retired
	Retired Retired

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

Quota to (b)(4) should be reduced by at least the total kilogram amounts sold by the company to the above listed customers.

2

If you have any questions pertaining to this information, please feel free to contact $me_{(C)}^{(b)(6);(b)(7)}$ or SC (b)(6);(b)(7)(C)



Subject	Date
Quota Letters Received as of October 14, 2011 (DFN: 630-08.2)	OCT 2 0 2011
То	From Dennil). 1.119 19 Barbara J. Boockholdt, Chief
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control

On October 14, 2011, this section received your e-mail requesting a review of five (5) quota applications of four (4) registered manufactures to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

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

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

Per consultation with the DEA Atlanta Field Division, further investigation/review is needed for the quota request of (b)(4) DEA number (b)(4);(b)(7)(E) due to a name change.

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

If you have any questions per	taining to this information, please feel free	to contact me $\frac{(b)(6);(b)(7)}{(b)}$ or PA
(b)(6);(b)(7)(C)		C)

(b)(4)

(b)(4)

Г

			(b)(6);(
	(E	D)(4)	
October 10, 2011	//	87	OCEIU
Dr. Christine Sannerud, PH.D. Drug Enforcement Administration Office of Diversion Control 8701 Morrissette Drive Alexandria Virginia 22301	11 ₈₈₄	۲	DICTON CEINED
RE: Additional Procurement Quota for Meth Registration Number ^{(b)(7)(E)}	nylphenidate HCl		
Dr. Sannerud:			
This letter is to request additional procurement e Methylphenidate HCl anhydrous base.	$\frac{1}{2} \int \int$	DEA code 1724)	
(b)(4)			
⁴) is providing the following data as support f	for the additional quot	a request	
(b)(4);(b)(7)(E) (b)(4)	Base (kg)		
l]	

		(b)(4)]
		We also request that your offi	ce consider a
pending return of (b)(4)	If considered, our total quota reque	st is:
(b)(4)	kg].	_	

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

Sincerely,	_ i k	
(b)(6)		

Director, Materials Management

(b)(6);(b)(7)(C)		
From: Sent: To: Subject:	(b)(6);(b)(7)(C) <u>Tuesdav. October 18</u> , 2011 5:29 PM (b)(6);(b)(7)(C) RE: Quota Request ^{(b)(4)}	(Letters Received as of October 14, 2011)

[b)(6);(b)(7)(C] this company is changing ownership, have not seen anything requesting the change of name/ownership yet. Did they indicate anything in their request? However, they are on our work plan FY 12 and the DI is aware of the anticipated change of name and ownership. Let me know if I can do anything else.

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

Group Supervisor

DEA Atlanta Division

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

- Office - Cell

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

Theodore Roosevelt

From: ^{(b)(6);(b)(7)(C)}		
Sent: Tuesday, October 18	2011 4:15 PM	
To: (b)(6);(b)(7)(C)		
Cc:		
Subject: Quota Request (b	(Letters Received as of October 14, 201	1)
Importance: High		-,
Subject: Quota Request	(Letters Received as of October 14, 201	1

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

The request I sent for $\binom{(b)(4)}{(b)(4)}$ has another name, have they requested a name change, or is this change of ownership (reason for name change)? RICS do not reflect the new name, SEE BELOW.

 From:
 (b)(6);(b)(7)(C)

 Sent:
 Tuesday, October 18, 2011 4:08 PM

 To:
 (b)(6);(b)(7)(C)

 Subject:
 RE:
 Quota Letters Received as of October 14, 2011

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

According to the documentation received from each company the names are correct:

• (b)(4)

CSA has yet to be updated with the current information.

Thanks,

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

Program Analyst Quota Unit (ODQ) UN Reporting and Quota Section Office of Diversion Control Drug Enforcement Administration ^{(b)(6);(b)(7)(C)}

 From: (b)(6);(b)(7)(C)

 Sent: Tuesday, October 18, 2011 11:57 AM

 To: (b)(6);(b)(7)(C)

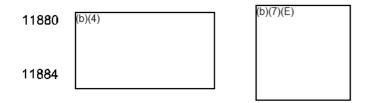
 Cc: Boockholdt, Barbara J.;(b)(6);(b)(7)(C)

 Subject: RE: Quota Letters Received as of October 14, 2011

 Importance: High

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

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



From: Boockholdt, Barbara J. Sent: Friday, October 14, 2011 5:31 PM To:^{[b)(6);(b)(7)(C)} Subject: FW: Quota Letters Received as of October 14, 2011

Barbara J. Boockholdt, Chief Regulatory Section Office of Diversion Control (b)(6);(b)(7)(C) desk

^{(b)(6);(b)(7)(C)} - desk - fax - cell

From:(b)(6);(b)(7)(C)	
Sent: Friday, October 14, 2011 4:42 PM	
To: Boockholdt, Barbara J. (b)(6);(b)(7)(C)	
Cc: (b)(6);(b)(7)(C)	Hill, Robert L.
Subject: Quota Letters Received as of October 14, 2011	

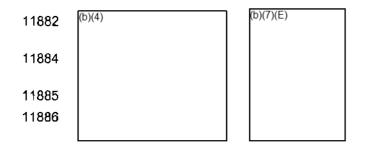
Good Afternoon,

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

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

Thank you in advance.

Log In #	Company Name	Registration #
11880	(b)(4)	(b)(7)(E)



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

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



Subject

Quota Letters Received as of October 7, 2011 (DFN: 630-08.2) Date

OCT 3 1 2011

То

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

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

On October 7, 2011, this section received your e-mail requesting a review of thirty-eight (38) quota applications from twenty-six (26) registered manufacturers to determine if there are any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

	(b)(4);(b)(7)(E)
Actavis Elizabeth LLC (109554)	
Actavis Southatlantic LLC (109591)	
Akorn, Inc. (109553)	
Akorn, Inc. (109552)	
Cerilliant Corporation (109590)	
Corepharma, LLC (109545)	
Corepharma, LLC (109546)	
DPT Lakewood, LLC (109547)	
Halo Pharmaceutical, Inc (109588)	
Halo Pharmaceutical, Inc (11878)	
Hisamitsu California Laboratories (11879)	
Hospira, Inc. (109595)	
Johnson Matthey, Inc. (109558)	
Johnson Matthey, Inc. (11876)	
KVK Tech, Inc. (11870)	
KVK Tech, Inc. (11872)	
KVK Tech, Inc. (11873)	
KVK Tech, Inc. (11874)	
KVK Tech, Inc. (11875)	

	(b)(4);(b)(7)(E)	ו	
Medisca, Inc. (109585)			
Noramco, Inc. (109531)			
Noramco, Inc. (109532)			
Noramco, Inc. (109544)			
OHM Laboratories, Inc (109582)			
OHM Laboratories, Inc (109583)			
Quality Assurance (11869)			
Sandoz (form. Geneva Pharmaceuticals, Inc) (11877)			
Siegfried (USA) (109543			
Specialty Compounding, LLC. (109534)			
Spectrum Laboratory Products (109589)			
Stat RX USA, LLC (109536)			
Stat RX USA, LLC (109537)			
Stat RX USA, LLC (109538)			
Stat RX USA, LLC (109539)			
Stat RX USA, LLC (109540)			
Tedora Pharma (109564)		0	(b)(6);(b)(7)(C);(
United Pharmacopeial Convention Inc. (109584)		k	b)(7)(F)
(b)(6);(b)(7)(C);(b)(7) (F)			
Per consultation with the field office, ODGR received an email f	from GS	pf the Lo	os
Angeles Field Division requesting the cancellation of quota from	Med-Pharmex	, Inc. #11871 (DEA	
(b)(4);(b)(7)(E) DI (LAFD) receive	d this request v	ria an email from (b)(
of Med-Pharmex, Inc. Based on this information, ODG	suggests that yo	ou cancel the quota for	or
Phenylpropanolamine (PPA).			

 $\frac{(b)(6);(b)(}{7)(C)}$ 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 per	aining to this information, please feel free	to contact me ^{(b)(6);(b)}	(7)(or PA
(b)(6);(b)(7)(C)			

Sent: [To: [Subject: [FYI [From: [b](6);(b)(7)(C) Sent: Monday, October 24, To: [b](6);(b)(7)(C))(6);(b)(7)(C) Monday, October 24, 20 b)(6);(b)(7)(C) FW: PPA Quota for Med		
From: ^{(b)(6);(b)(7)(C)} Sent: Monday, October 24, To: ^{(b)(6);(b)(7)(C)}	1		
Sent: Monday, October 24, To: (b)(6);(b)(7)(C)			
Subject: FW: PPA Quota for			
I will get Mr. $\frac{(b)(6);(b)(7)}{(C)}$ to c PPA via letter/tax.	ancel his request for th	e addition of drug code for	
Please tell the HQS quota of her annual allotments. I	lady ^{(b)(6);(b)(7)(C)} have never been in di	he had contacted you last w ect contact with her.	cek about Med-Phm and the setting
From: (b)(6);(b)(7)(C) mail Sent: Saturday, October 22 To: (b)(6);(b)(7)(C) 3 Subject: PPA Quota for Me	, 2011 12:26 PM	<u>ex.com]</u> (b)(6);(b)(7)(C)	
(b)(6);(b)(7)(C) (b)(4)			
So, plcase cancel our requ Thank you Regards (b)(6) Med-Pharmex, Inc. 2727 Thompson Creek Re		year.	
Pomona, CA 91767-1861 Phone: ^{(b)(6)} Fax: ^{(b)(6)}			



Subject

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

Date

NOV 04 2011.

Т٥

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

From Boachho idt Barbara J. Boockholdt, Chief

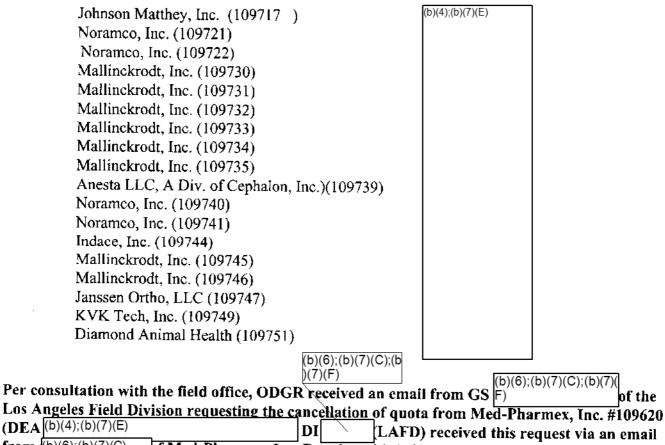
Regulatory Section Office of Diversion Control

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

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

QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION

Prof Compounding Ctrs. of America (109596)	(b)(4);(b)(7)(E)
Prof Compounding Ctrs. of America (109598)	
Corepharma, LLC (109601)	
Vista Pharm, Inc. (109602)	
Actavis Southatlantic LLC (109591)	
KVK Tech, Inc. (109614)	
KVK Tech, Inc. (109615)	
KVK Tech, Inc. (109615)	
KVK Tech, Inc. (109616)	
KVK Tech, Inc. (109617)	
Mallinckrodt, Inc. (109618)	
Almac Clinical Services, Inc. (109671)	
Siegfried (USA) (109683)	
Siegfried (USA) (109684)	
Siegfried (USA) (109686)	
KVK Tech, Inc. (109688)	
Catalent Pharma Solutions, Inc. (109690)	
Anderson Packaging, Inc. (109692)	
Almac Clinical Services, Inc. (109708)	
Johnson Matthey, Inc. (109716)	



from (b)(6);(b)(7)(C) pf Med-Pharmex, Inc. Based on this information, ODG suggests that you cancel the quota for Phenylpropanolamine (PPA).

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

If you have any questions pertaining to this information, please feel free to contact me $\binom{(b)(6);(b)(7)()}{C}$ or PA

-



Subject	D-1-
Quota Letters Received as of November 1, 2011 (DFN: 630-08.2)	Date
	NOV 0 4 2011
То	From Damid). A day to
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control
On November 1, 2011, this section received your e-mail a quota applications from twenty-six (26) registered manufa administrative/legal actions against these applicants and t	acturers to determine if there are any new di-
ODGR conducted regions (MADDIG (GRA (A))	
ODGR conducted reviews (NADDIS, CSA, etc), as well a input and recommendations. Provided below on the	as surveyed the responsible field offices for their
input and recommendations. Provided below are the resu	Its and recommendations.
QUOTA APPLICANTS WITH NO ADVERSE (OR DEROGATORY INFORMATION
Halo Pharmaceutical Inc. (109760)	(b)(4);(b)(7)(E)
Prof Compounding Centers of (109761)	
Mallinckrodt LLC (109762)	
Prof Compounding Centers of (109763)	
Nesher Pharmaceuticals USA LLC (109774)	
Noramco Inc. (109775)	
Nesher Pharmaceuticals USA LLC (109777)	
Watson Laboratories Inc. (109778)	
West-Ward Pharmaceuticals Corp (109779)	
Nesher Pharmaceuticals USA LLC (109780)	
Nesher Pharmaccuticals USA LLC (109781)	
Catalent Pharma Solutions, Inc. (109782)	
Catalent Pharma Solutions, Inc. (109783)	
Nesher Pharmaceuticals USA LLC (109784)	
Nesher Pharmaceuticals USA LLC (109786)	
Nesher Pharmaceuticals USA LLC (109787)	
Mallinckrodt LLC (109788)	
Paddock Laboratories LLC (109798) Paddock Laboratories LLC (109798)	
Paddock Laboratories LLC (109799)	
Paddock Laboratories LLC (109801)	
Paddock Laboratories LLC (109802)	

(b)(4);(b)(7)(E) Paddock Laboratories LLC (109803) Johnson Matthey Inc. (109804) Johnson Matthey Inc. (109805) Johnson Matthey Inc. (109806) Akorn, Inc. (109812) Akorn, Inc. (109815) Noramco Inc. (109816) Catlent Pharma Solutions, Inc. (109823) Vista Pharm Inc. (109830) Elan Holdings Inc. (109831) Elan Holdings Inc. (109835) Paddock Laboratories Inc. (109845) Paddock Laboratories Inc. (109846) Vista Pharm Inc. (109846) Alltech Associates Inc. (109863) Cambrex Charles City (109875) Generic Pharmaceutical Svc In (109880) Great Southern Laboratories (109891) Cambrex Charles City (109911)

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

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

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

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

6. - ²

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ODG is recommending that ODQ deny the quota increase for $(b)(4)$	4) based upon the show
stated information.	⁴⁾ based upon the above

If you have any questions	pertaining to this information, please feel free to contact $me_{(C)}^{(b)(6);(b)(7)}$ or SC
(b)(6);(b)(7)(C)	or SC



Subject	Date
Quota Letters Received as of October 17, 2011 (DFN: 630-08.2)	
	NOV_1.0 2011
То	From Deally All
Christine A. Sannerud, Ph.D., Chief	From Daniel J. A. H. M. Barbara J. Boockholdt, Chief M
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control
Reference is made to your October 17, 2011 e-mail reque applications from nineteen (19) registered manufacturers administrative/legal actions against these applicants and to	to determine if there are any pending
One of the above stated requests was from Med-Pharmex, Pharmex, in its letter, requested an increase for Phenylpro requested their request for Phenylpropanolamine be withd Pentobarbital. On November 9, 2011, SC ^{(b)(6);(b)(7)(C)}	panolamine (PPA) and Pentobarbital but later rawn. ODGR did not address the request for contacted the Los Angeles Field Division as
well as conducted checks in the various databases. No de	rogatory information was found.

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

If you have any questions pertaining to this information, please feel free to contact $me_{C}^{(b)(6),(b)(7)(C)}$ or SC



Subject Quota Letters Received as of November 8, 2011 (DFN: 630-08.2)	Date NOV_1 0 2011.
То	From
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief 17
Drug & Chemical Evaluation Section	Regulatory Section
Office of Diverison Control	Office of Diversion Control
On November 8, 2011, this section received your c-ma applications of registered manufactures to determine if actions against these applicants and to advise ODE of t	there were any pending administration /
ODGR conducted reviews (NADDIS, CSA, etc), as we input and recommendations. Provided below are the re-	ell as surveyed the responsible field offices for their esults and recommendations.
QUOTA APPLICANTS WITH NO ADVERSI	E OR DEROGATORY INFORMATION
Anesta (11887)	(b)(4);(b)(7)(E)
KP Pharmaceutical (11888)	
Metrics (11889)	
King Pharmaceuticals (11890)	

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.

DSM Pharmaceuticals (11891) Vintage Pharmaceuticals (11892)

Mylan Chestnut Ridge Road, WV (11893) (1 of 2)

Mylan Pharmaceuticals (11893) (2 of 2)

If you have any questions pertaining to this information, please feel free to contact $me_{(C)}^{(b)(6);(b)(7)}$ or SC

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Subject	Date
Quota Letters Received as of November 15, 2011 (DFN: 630-08.2)	
	NOV 1 6 2011
То	From Obacity Ailly ha
Christing & Sannanud Dh D. Chief	Lung . Jun M
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evaluation Section Office of Diversion Control	Regulatory Section
Office of Divenson Control	Office of Diversion Control
applications of fourteen (14) registered manufactures to administrative/legal actions against these applicants and ODGR conducted reviews (NADDIS, CSA, etc), as wel input and recommendations. Provided below are the res QUOTA APPLICANTS WITH NO ADVERSE	to advise ODQ of the findings. 1 as surveyed the responsible field offices for their sults and recommendations.
	(b)(4);(b)(7)(E)
King Pharmaceuticals (11895)	
Pathcon Pharmaceuticals Inc (109923)	
Mallinckrodt LLC (109925)	
DSM Pharmaceuticals, Inc (109929)	
Watson Laboratories Inc-Florida (109935)	
LNK International Inc (109936) EON Labs, Inc. (109945)	
EON Labs, Inc. (109945) EON Labs, Inc. (109949)	
US Compounding, Inc (109949)	
EON Labs, Inc. (109952)	
Metrics (109963)	
Chemtos, LLC (109967)	
EON Labs, Inc. (109974)	
EON Labs, Inc. (109980)	
AAIPharma Services Corp (109981)	

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Patheon Pharmaceuticals Inc (109999)

AKORN, Inc (110028) AKORN, Inc (110029) Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

If you have any questions pertaining to this information, please feel free to contact me $\begin{bmatrix} (b)(6);(b)(7)(C) \\ C \end{bmatrix}$ or SC



Subject (b)(4) 2011 Procurement Quota Increase Request Oxycodone (For Sale) (DFN: 630-08.2)	Date NOV 1 6 2014
То	From Daniel). Ally M
Christine A. Sannerud, Ph.D., Chief	Barbara J. Boockholdt, Chief
Drug & Chemical Evalutaion Section (ODQ)	Regulatory Section (ODG)
Office of Diversion Control	Office of Diversion Control
NADDIS to determine if there were any open field invest also run through RICS to determine if the registrations v	on order. The names of the customers were run through stigations. The DEA registration numbers were
the customers had no derogatory information.	
DEA does not have sufficient grounds to limit, restrict, of Based on this information, ODG suggests that you proce by $^{(b)(4)}$ for the quota increase.	
The below listed customer was found to have derogatory	information against its registration:
Cu	rrently Under Review/Investigation
(b)(4);(b)(7)(E)	

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

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



Subject (b)(4),(b)(7)(E) 2011 Procurement Quota Increase Request Osycodone (DFN: 630-08.2)	Date DEC 0 6 2011_
To Christine A. Sannerud, Ph.D., Chief Drug & Chemical Evalutaion Section (ODQ) Office of Diversion Control	From Barbara J. Boockholdt, Chief Regulatory Section (ODG) Office of Diversion Control
On November 17, 2011, this section received your m submitted by $(b)(4)$ ODQ is requesting a review information on whether the applicant's customers are order to show cause or immediate suspension order. ODGR conducted NADDIS and CSA reviews of app (b)(4) customers as well as an in-depth invest	w of $(b)(4)$ customer list, specifically, re currently under investigation or are subject of an proximately one hundred and thirty-two (132) of
The below listed information was found on (b)(4)	customers: Currently Under Review/Investigation
(b)(4);(b)	Currently Under Review/Investigation
(b)(4);(b)	Currently Under Review/Investigation
(b)(4);(b)(7)(Currently Under Review/Investigation
(b)(4);(b)(7)(E	Currently Under Review/Investigation

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	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	
(b)(4);(b)(Currently Under Suspension (7)(E)
(b)(4);(b)(5);(b)	Currently Under Review/Investigation
(b)(4);(b)(7)(E)	Currently Under Review/Investigation
(b)(4);(b)(7)(Currently Under Review/Investigation
)(4);(b)(7)(E)	Retired
a)(4);(b)(7)(E)	Retired
b)(4);(b)(7)(E)	Retired

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

Quota to (b)(4) should be reduced by at least the total kilogram amounts sold by the company to the above listed customers.

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



Subject

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

Date

DEC 1 3 2011

То

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

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

On December 2, 2011, this section received your e-mail requesting a review of one hundred ninety-seven (197) initial quota requests from registered manufacturers to determine if there were any pending administrative/legal actions against these applicants and to advise ODE of the findings.

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

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

QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

(b)(4);(b)(7)(E)		
/h\//h\/6\-/h\/7\/C\-/h\/7\/E\-/h\/7\/E\		
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)		
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)		
(b)(4);(b)(7)(E)		
U)(4),(U)(7)(L)		

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

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

If you have any questions pertaining to this information, please feel free to contact $me_{(D)(G);(D)(7)(C)}^{(b)(G);(D)(7)(C)}$ or SC