Initial MQ for 2011

BASIC CLASS:	**2011 Initial Quota Worksheet**		9050					
PQ Total:	33,005.748 kg					**FDA Est.:**	-4.60%	
Company:	(b)(4)							
Request:	10.000	128	327.000	16,300.000	20,060.000	5,600.000	42,425.000	requested
Current Year MQ:	52.000	0	450.000	18,000.000	10,013.000	3,750.000		
Prev. Year's Sales:	-	0	214.156	13,126.060	10,900.660	1,122.365		
Total Prev. Year's Sales:	25,363.279	25,363.279	25,363.279	25,363.279	25,363.279	25,363.279		
% of Prev. Year's Sales:	0%	0%	1%	52%	43%	4%		
Share of Next Year's PQs:	-	-	278.686	17,081.207	14,185.249	1,460.556		
Prev. Yr. Year-end Inv.:	-	0	419.485	6,148.841	7,405.802	248.534		
Proj. Exports Current Year:	-	0	-	865.800	-	-		
Company est. current year sale	-	92	185.000	19,157.571	13,948.000	3,777.700		
Proj. Exports Next Year:	-	0	-	740.000	-	-		
Company's Proj. Inv. Current Y	-	0	300.183	7,722.195	6,447.000	893.580		
DEA's Proj. Inv. Current Year:	52.000	(92.000)	684.485	4,125.470	3,470.802	220.834		
INITIAL MQs								
2/3 calculation	34.667	0	579.657	16,099.227	11,612.535	2,665.689		
Calc. Using Company's Inv.:	-	-	117.845	18,639.616	14,830.874	1,297.254		
Calc. Using DEA's Inv.:	(52.000)	92.000	(266.457)	22,236.341	17,807.072	1,970.000		
Calc. w/ CFR 50% inventory	(39.000)	92.000	(223.628)	21,726.039	16,764.010	2,542.361		
Further Calculation:	10.000	92.000	327.000	16,300.000	16,837.000	2,540.000		
MQ:	10.000	92.000	327.000	16,300.000	16,837.000	2,540.000		
Total Initial MQs:	36,106.000	+ others	3.105	=	36,109.105			

FURTHER CALCULATIONS

Initial

Update numbers below

MQs 2011	42,428.105
Final 2011	39,605.000
Initial APQ	39,605.000

FDA est: APQ last year * est = 37,783.170

Initial MQs 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**			**9050**								
Company:	(b)(4)											
Request:	1946				19400				30000			
Current Year MQ:	280				14000				32556			
Prev. Yr. Year-end Inv.:	0				1,968.703				6,850.682			
Company's Proj. Inv. Current Yr.:	0				1,971.697				6,661.666			
Calculations	**amt. needed**	**substance**	**MQ**	**yield**	**amt. needed**	**substance**	**MQ**	**yield**	**amt. needed**	**substance**	**MQ**	**yield**
(based on request MQ)	331	hydrocodon	281.0	85%	5,633.803	hydrocodor	4,000.0	71%	23,913.043	hydrocodone	22,000.000	92%
					1,587.302	oxycodone	1,000.000	63%	304.878	dihydrocodei	250.000	82%
					344.211	codeine (sr	327.000	95%				
total need	331				7,565.315				24,217.922			
INITIAL MQs												
ost need	483.235				10,984.947				31,749.736			
MQ:	484.000				11,000.000				30,000.000			
Total Initial MQs:	41484	+ others		=	41,484.000							
FURTHER CALCULATIONS												
						MQs 2010			47,961.000			
						MQs 2011			51,442.000			
						Final 2011			65,000.000			

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2011Initial Quota Worksheets**	9145	
	3452.01		
Company:	(b)(4)		
Request:	592	760	2100
Current Year MQ:	296	637	2674
Prev. Yr. Year-end Inv.:	24	10	638
Proj. Exports Next Year:	0	-	0
Company's Proj. Inv. Current Yr.:	0	0.022	580

Caluclations:	amount neededd	substance	MQ	yeild	amount needed	substance	MQ	yeild	amount needd	substance	MQ	yeild
	270.7692308	hydromorphone	176.000	65%	601.515	hydromorphone	397.000	66%	1,961.538	hydromorphc	1,020.000	52%
Total needed:	270.7692308				601.515				1,961.538			
INITIAL MQs												
estimated need	412.462				911.122				2540.443			
MQ:	200.000				716.000				2,100.000			
Total Initial MQs:	3016	+ others	0.010	=	3,016.010							

FURTHER CALCULATIONS

Update numbers below

MQs 2010	3,607.006
MQs 2011	3,452.010
Final 2010	3,608.000
Initial APQ	3,608.000

Initial MQ 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**							
PQ Total:	1,520.206 kg					**FDA Est.:**	3.40%	
Company:	(b)(4)							
Request:	288.000	200.000	52.000	300.000	610.000			Initial
Current Year MQ:	72.000	85.000	22.500	500.000	620.000			
Prev. Year's Sales:	40.221	17.426	2.550	439.236	630.519			
Total Prev. Year's Sales:	1,129.952	1,129.952	1,129.952	1,129.952	1,129.952			
% of Prev. Year's Sales:	4%	2%	0%	39%	56%			
Share of Next Year's PQs:	54.112	23.444	3.431	590.936	848.283			
Prev. Yr. Year-end Inv.:	58.120	11.285	-	531.749	248.064			
Proj. Exports Current Year:	-	24.178	-	-	80.488			
estimated sales current year:	89.900	88.500	20.330	340.000	594.146			
Proj. Exports Next Year:	22.400	50.000	2.000	-	101.000			
Company's Proj. Inv. Current Yr.:	10.000	10.000	8.304	500.115	260.005	788.424		
DEA's Proj. Inv. Current Year:	40.220	(16.393)	2.170	691.749	193.430			
INITIAL MQs								
2/3 calculation	86.747	64.190	15.000	687.833	578.709	1,432.479		
Calc. Using Company's Inv.:	82.746	70.478	(1.844)	268.102	943.763			
Calc. Using DEA's Inv.:	52.526	96.871	4.290	76.468	1,010.338			
calc. w/ CFR 50% inventory	45.420	66.949	7.743	171.921	1,021.923			
Further Calculation:	45.000	70.000	8.000	300.000	610.000			
MQ:	45.000	70.000	8.000	300.000	610.000			
Total Initial MQs:	1,033.000	+ others	0.007	=	1,033.007			
FURTHER CALCULATIONS								Initial
Update numbers below								
						MQs 2010		1,300.603
						MQs 2011		1,453.207
						Final 2010		1,428.000
						Initial APQ		1,428.000
FDA est: APQ last year * est =	1476.552							

Initial MQ 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**		9193				
PQ Total:	71,342.082 kg					**FDA Est.:**	5.90%
Company:	(b)(4)						
Request:	100.000	1,763.000	9,295.000	23,000.000	24,900.000	3,300.000	10,500.000
Current Year MQ:	-	281.000	4,135.000	22,000.000	24,675.000	-	2,697.000
Prev. Year's Sales:	-	-	2,565.110	28,154.154	14,205.021	16.434	64.615
Total Prev. Year's Sales:	52,131.180	52,131.180	52,131.180	52,131.180	52,131.180	52,131.180	52,131.180
% of Prev. Year's Sales:	0%	0%	5%	54%	27%	0%	0%
Share of Next Year's PQs:	-	-	3,510.381	38,529.263	19,439.724	22.490	88.426
Prev. Yr. Year-end Inv.:	-	-	3,105.981	7,532.469	3,379.779	1,132.834	2,761.049
Proj. Exports Current Year:	-	-	-	6.100	-	-	-
estimated sales current year:	-	150.000	3,693.395	20,220.441	23,171.000	800.000	3,050.000
Proj. Exports Next Year:	-	-	-	28.280	-	-	-
Company's Proj. Inv. Current Yr.:	30.225	48.000	2,086.887	9,311.974	6,540.000	300.000	1,223.160
DEA's Proj. Inv. Current Year:	-	131.000	3,547.586	9,305.928	4,883.779	332.834	2,408.049
INITIAL MQs							
2/3 calculation	-	187.333	4,827.321	19,688.313	18,703.186	755.223	3,638.699
Calc. Using Company's Inv.:	(30.225)	(48.000)	2,476.608	40,804.348	18,731.642	(270.763)	(1,108.206)
Calc. Using DEA's Inv.:	-	(131.000)	1,015.909	40,810.394	20,387.863	(303.597)	(2,293.095)
Calc. using CFR 50% inventory	-	(60.750)	1,874.140	44,355.651	25,584.627	(304.721)	(1,623.266)
Further Calculation:	-	281.000	4,000.000	22,000.000	23,400.000	1,500.000	2,700.000
MQ:	-	281.000	4,000.000	22,000.000	23,400.000	1,500.000	2,700.000
Total Initial MQs:	53,881.000	+ others	0.025	=	53,881.025		

FURTHER CALCULATIONS

Update numbers below

MQs 2010	54,419.021
MQs 2011	73,438.025
Final 2008	55,000.000
Initial APQ	55,000.000

(b)(4) no justificaiton

(b)(4) no justification

FDA est: APQ * est = 58245

Initial MQ 2011

BASIC CLASS: **2011 Initial Quota Worksheets**

PQ Total: 3597.593 (less packaging/transfer quotas) **FDA Est.:** 8.20%

Company:	(b)(4)						
Request:	20.000	156.000	384.000	386.851	293.700	1,020.000	1,770.000
Current Year MQ:	-	156.000	192.000	400	300.000	1,174.000	898.000
Prev. Year's Sales:	-	-	15.757	183.335	209.514	1,168.740	662.459
Total Prev. Year's Sales:	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272
% of Prev. Year's Sales:	0%	0%	1%	8%	9%	49%	28%
Share of Next Year's PQs:	-	-	23.805	276.980	316.531	1,765.716	1,000.834
Prev. Yr. Year-end Inv.:	-	-	2.630	46.550	116.076	582.181	654.287
Proj. Exports Current Year:	-	-	-	110.000	1.780	22.250	-
company's est. current year sales	-	153.000	183.000	226.000	241.220	1,273.805	1,050.000
Proj. Exports Next Year:	-	-	-	120.580	-	22.250	-
Company's Proj. Inv. Current Yr.:	-	3.000	-	74.000	124.768	508.946	0.350
DEA's Proj. Inv. Current Year:	-	3.000	11.630	110.550	173.076	460.126	502.287
INITIAL MQs							
2/3 calculation	-	104.000	129.753	297.700	277.384	1,170.787	1,034.858
Calc. Using Company's Inv.:	-	(3.000)	35.708	462.050	350.028	2,161.878	1,500.901
Calc. Using DEA's Inv.:	-	(3.000)	24.078	425.500	301.720	2,210.698	998.964
Calc. using CFR 50% inventory	-	36.000	66.127	335.675	297.588	2,040.519	973.255
Further Calculation:	20.000	156.000	65.000	387.000	294.000	1,020.000	929.000
MQ:	20.000	156.000	65.000	387.000	294.000	1,020.000	929.000
Total Initial MQs:	2,871.000	+ others	0.025	=	2,871.025		

FURTHER CALCULATIONS

Update numbers below

MQs 2010	3,160.021
MQs 2011	4,031.276
Final 2010	3,455.000
Initial APQ	3,455.000

FDA est: APQ * est = 3738.310

Initial MQ 2011

BASIC CLASS:	**2011 Initial Quota Worksheet**		9230				
PQ Total:	4,392.220 kg					**FDA Est.:**	-12.00%
Company:	(b)(4)						
Request:	0.005	3,800.000	0.002	46.000	1,220.000		Initial
Current Year MQ:	0.001	2,917.000	0.002	46.000	950.000		
Prev. Year's Sales:	-	2,604.998	-	-	1,182.210		
Total Prev. Year's Sales:	3,787.208	3,787.208	3,787.208	3,787.208	3,787.208		
% of Prev. Year's Sales:	0%	69%	0%	0%	31%		
Share of Next Year's PQs:	-	3,021.150	-	-	1,371.070		
Prev. Yr. Year-end Inv.:	0.001	1,837.052	0.002	-	845.855		
Proj. Exports Current Year:	-	419.100	-	-	69.600		
Company est. sales current yr.	0.001	3,840.073	0.001	-	1,050.090		
Proj. Exports Next Year:	-	-	-	-	69.600		
Company's Proj. Inv. Current Yr.:	0.001	183.335	0.001	-	508.774		
DEA's Proj. Inv. Current Year:	0.001	494.879	0.003	46.000	676.165		
INITIAL MQs							
2/3 calculation	0.001	3,169.368	0.003	30.667	1,197.237		
Calc. Using Company's Inv.:	(0.001)	4,348.390	(0.001)	-	1,617.431		
Calc. Using DEA's Inv.:	(0.001)	4,036.846	(0.003)	(46.000)	1,450.040		
calc. using CFR 50% inventory	(0.001)	4,010.809	(0.003)	(34.500)	1,275.172		
Further Calculation:	0.005	3,800.000	0.002	46.000	1,220.000		
MQ:	0.005	3,800.000	0.002	46.000	1,220.000		
Total Initial MQs:	5,066.007	+ others		=	5,066.007		

FURTHER CALCULATIONS Initial

Update numbers below

MQs 2010	3,913.003
MQs 2011	5,066.007
Final 2010	6,600.000
Initial APQ	6,600.000

FSA est: APQ last year * est = 5808

Initial MQs 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**			9250			
PQ Total:	18,471.411	kg				**FDA Est.:**	4.00%
Company:	(b)(4)						
Request:	4,884.000	0.004	316	-	11,000.000	3,960.000	Initial
Current Year MQ:	3,056.500	0.004	80	-	12,000.000	2,900.000	
Prev. Year's Sales:	3,047.554	0.002	0	-	11,323.016	2,224.618	
Total Prev. Year's Sales:	16,595.190	16,595.190	16,595.190	16,595.190	16,595.190	16,595.190	
% of Prev. Year's Sales:	18%	0%	0%	0%	68%	13%	
Share of Next Year's PQs:	3,392.105	0.002	-	-	12,603.175	2,476.129	
Prev. Yr. Year-end Inv.:	1,691.711	0.005	0	-	4,988.682	665.346	
Proj. Exports Current Year:	-	-	14	-	1,780.000	-	
company est. sales current year	2,726.960	0.002	42	-	9,432.265	2,296.200	
Proj. Exports Next Year:	-	-	105	-	1,780.000	-	
Company's Proj. Inv. Current Yr.:	1,316.700	0.004	20	-	4,059.425	795.000	
DEA's Proj. Inv. Current Year:	2,021.251	0.007	24.000	-	5,776.417	1,269.146	
INITIAL MQs							
2/3 calculation	3,165.474	0.006	53.333	-	11,325.788	2,376.897	
Calc. Using Company's Inv.:	3,093.036	(0.001)	85.000	-	14,104.702	2,423.968	
Calc. Using DEA's Inv.:	2,388.485	(0.004)	81.000	-	12,387.710	1,949.822	
calc. using CFR 50% inventory	2,983.005	(0.003)	(4.000)	-	12,977.552	2,551.015	
Further Calculation:	3,000.000	0.004	316	-	11,000.000	2,530.000	
MQ:	3,000.000	0.004	316.000	-	11,000.000	2,530.000	
Total Initial MQs:	16,846.004		+ others		=	16,846.004	

FURTHER CALCULATIONS

		Initial
Update numbers below		
	MQs 2010	18,036.504
	MQs 2011	20,160.004
	Final APQ	20,000.000
	Initial APQ	20,000.000

FDA est: APQ last year * est = 20800

Initial MQs 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**			9250			
PQ Total:	18,471.411	kg				**FDA Est.:**	4.00%
Company:	(b)(4)						
Request:	4,884.000	0.004	316	-	11,000.000	3,960.000	Initial
Current Year MQ:	3,056.500	0.004	80	-	12,000.000	2,900.000	
Prev. Year's Sales:	3,047.554	0.002	0	-	11,323.016	2,224.618	
Total Prev. Year's Sales:	16,595.190	16,595.190	16,595.190	16,595.190	16,595.190	16,595.190	
% of Prev. Year's Sales:	18%	0%	0%	0%	68%	13%	
Share of Next Year's PQs:	3,392.105	0.002	-	-	12,603.175	2,476.129	
Prev. Yr. Year-end Inv.:	1,691.711	0.005	0	-	4,988.682	665.346	
Proj. Exports Current Year:	-	-	14	-	1,780.000	-	
company est. sales current year	2,726.960	0.002	42	-	9,432.265	2,296.200	
Proj. Exports Next Year:	-	-	105	-	1,780.000	-	
Company's Proj. Inv. Current Yr.:	1,316.700	0.004	20	-	4,059.425	795.000	
DEA's Proj. Inv. Current Year:	2,021.251	0.007	24.000	-	5,776.417	1,269.146	
INITIAL MQs							
2/3 calculation	3,165.474	0.006	53.333	-	11,325.788	2,376.897	
Calc. Using Company's Inv.:	3,093.036	(0.001)	85.000	-	14,104.702	2,423.968	
Calc. Using DEA's Inv.:	2,388.485	(0.004)	81.000	-	12,387.710	1,949.822	
calc. using CFR 50% inventory	2,983.005	(0.003)	(4.000)	-	12,977.552	2,551.015	
Further Calculation:	3,000.000	0.004	316	-	11,000.000	2,530.000	
MQ:	3,000.000	0.004	316.000	-	11,000.000	2,530.000	
Total Initial MQs:	16,846.004		+ others		=	16,846.004	

FURTHER CALCULATIONS

			Initial
Update numbers below			
		MQs 2010	18,036.504
		MQs 2011	20,160.004
		Final APQ	20,000.000
		Initial APQ	20,000.000
FDA est: APQ last year * est =	20800		

Initial MQ 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**															
	2600															
Company:	(b)(4)															
Request:	2,823.000				435.000				14,000.000				3,300.000			
Current Year MQ:	-				220.000				12,800.000				4,100.000			
Prev. Yr. Year-end Inv.:	-				-				2,373.349				216.931			
Company's Proj. Inv. Current Yr.:	-				29.000				5,000.000				143.000			
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
	3,750.000	methadone	3,000.000	80%	421.333	methadone	316.000	75%	11,340.206	methadone	11,000.000	97%	2,750.000	methadone	2,530.000	92%
total need	3,750.000				421.333				11,340.206				2,750.000			
INITIAL MQs																
total x 50% inventory - prev. YEI	5,625.000				603.000				12,010.309				3,982.000			
MQ:	2,823.000				435.000				12,000.000				3,300.000			
Total Initial MQs:	18,558.000	+ others	0.004	=	18,558.004											

FURTHER CALCULATIONS

Update numbers below

(b)(4) estimated need:	5,625.000	MQs 2010	22,120.004
manufacturing	2823	MQs 2011	27,558.004
procuring	2802	Final 2010	26,000.000
		Initial APQ	26,000.000
(b)(4) need	2802		
est 2010 states	2698		
allowed YEI	1375		
total 2011 need	4177		
est 2010 YEI	1800		
	2,377.000		

Initial MQ 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**						
PQ Total:	42,928.416 kg					**FDA Est.:**	7.70%
Company:	(b)(4)						
Request:	32.000	2,218.000	17,000.000	13,432.000	362.000		Initial
Current Year MQ:	32.000	600.000	19,000.000	16,724.000	-		
Prev. Year's Sales:	-	700.599	17,008.165	12,859.872	-		
Total Prev. Year's Sales:	30,568.647	30,568.647	30,568.647	30,568.647	30,568.647		
% of Prev. Year's Sales:	0%	2%	56%	42%	0%		
Share of Next Year's PQs:	-	983.871	23,885.047	18,059.482	-		
Prev. Yr. Year-end Inv.:	-	813.818	7,703.440	4,437.083	-		
Proj. Exports Current Year:	-	4.500	539.119	-	-		
Proj. Exports Next Year:	-	4.500	225.000	-	-		
Company's est. sales current yr	-	750.000	16,983.697	12,647.000	-		
Company's Proj. Inv. Current Yr.:	-	305.818	5,839.000	8,037.000	-		
DEA's Proj. Inv. Current Year:	32.000	659.318	9,180.624	8,514.083	-		
INITIAL MQs							
2/3 calculation	21.333	942.545	17,802.293	14,107.389	-		
Calc. Using Company's Inv.:	-	1,174.489	30,213.571	19,052.223	-		
Calc. Using DEA's Inv.:	(32.000)	820.989	26,871.947	18,575.140	-		
Calc. using CFR 50% inventory	(32.000)	580.841	22,632.570	15,146.717	-		
Further Calculation:	32.000	620.000	17,000.000	13,432.000	362.000		
MQ:	32.000	620.000	17,000.000	13,432.000	362.000		
Total Initial MQs:	31,446.000	+ others	1,500.105	=	32,946.105		

FURTHER CALCULATIONS Initial

Update numbers below

MQs 2010	36,502.108
MQs 2011	34,771.605
Final 2010	39,000.000
Initial APQ	39,000.000

FDA est: APQ last year * est= 42003

Initial MQs 2011

BASIC CLASS: 2011nitial Quota Worksheets

Company:	(b)(4)																					
Request:	0			2950			Initial	44000			16997			5110.8								
Current Year MQ:	0			9100				50000			12500			4511								
Prev. Yr. Year-end Inv.:	0			561.591				12,864.841			5,560.558			37.984								
Company's Proj. Inv. Current Yr.:	0			394.615				13,395.959			8,434.000			42.932								
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield		
(based on request)	0	codeine		80%					16,522.727	codeine	16,300.000	88%	19,132.955	codeine	16,837.000	88%	-	codeine	-	91%		
	0	codeine for	-	80%	11,000.000	codeine for	11,000.000	100%	34,090.909	codein for co	30,000.000	88%	-	codeine for	-	88%						
					827.083	hydromorpl	397.000	48%	1,888.889	hydromorphc	1,020.000	54%										
					720.930	morphine s	620.000	86%	2,210.526	dihydromorpl	2,100.000	95%										
total need	-				12,548.014				56,713.052				19,132.955									
INITIAL MQs																						
estimated need	-				17,565.402				69,595.355				18,607.193				1,084.818					
MQ:	-				2,950.000				44,000.000				17,000.000				-					
Total Initial MQs:	63,950.000	+ others	=	63,950.000																		
FURTHER CALCULATIONS						MQs 2010			76,355.000													
						MQs 2011		Initial	69,585.800													
						Final 2010			83,000.000													
						Initial APQ			83,000.000													

Morphine (ISC conversion) Init

Initial MQ 2011

BASIC CLASS:	**2011 Initial Quota Worksheets**								
PQ Total:	100,447.547 kg						**FDA Est.:**	9.00%	
Company:	(b)(4)								
Request:	816.000	-	5,400.000	24,000.000	39,650.000	#REF!	43,000.000	1.000	
Current Year MQ:	408.000	#REF!	4,003.400	28,000.000	34,714.000	#REF!	37,221.000	-	
Prev. Year's Sales:	132.931	-	1,094.884	24,292.917	21,652.557	#REF!	24,572.476	175.534	
Total Prev. Year's Sales:	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	
% of Prev. Year's Sales:	0%	0%	1%	32%	28%	#REF!	32%	0%	
Share of Next Year's PQs:	173.500	-	1,429.033	31,706.892	28,260.719	#REF!	32,071.770	229.105	
Prev. Yr. Year-end Inv.:	-	#REF!	629.362	11,970.122	8,581.363	#REF!	7,465.353	681.368	
Proj. Exports Current Year:	-	-	2.610	2.219	1,100.000	-	7,000.000	-	
estimated sales current year:	67.705	-	3,597.390	25,035.179	36,344.000	-	25,000.000	59.900	
Proj. Exports Next Year:	-	-	-	8.700	1,100.000	-	10,000.000	-	
Company's Proj. Inv. Current Yr.:	41.000	-	1,536.506	9,405.000	7,810.000	21.400	7,500.000	647.961	
DEA's Proj. Inv. Current Year:	340.295	#REF!	1,032.762	14,932.724	5,851.363	#REF!	12,686.353	621.468	-
INITIAL MQs									
2/3 calculation	272.000	#REF!	3,088.508	26,646.748	28,863.575	#REF!	29,790.902	454.245	#REF!
Calc. Using Company's Inv.:	184.550	-	321.236	31,822.660	30,028.934	#REF!	44,193.301	(350.124)	
Calc. Using DEA's Inv.:	(114.745)	#REF!	824.980	26,294.936	31,987.571	#REF!	39,006.948	(323.631)	
calc. using CFR 50% inventory	(90.187)	#REF!	1,027.250	30,774.121	34,887.675	#REF!	33,546.479	(291.203)	
Further Calculation:	175.000	-	1,000.000	24,000.000	33,500.000	-	32,000.000	-	
MQ:	175.000	-	1,000.000	24,000.000	33,500.000	-	32,000.000	-	
Total Initial MQs:	90,675.000	+ others	3.065	=	90,678.065				

FURTHER CALCULATIONS

Initial

Update numbers below

MQs 2010	##########
MQs 2011	##########
Final 2010	##########
Initial APQ	##########

FDA est: APQ last year * est= 114995

Initial MQs 2011

BASIC CLASS:	**2011 Initial Quota Worksheet**		9652					
PQ Total:	5,182.588 kg						**FDA Est.:**	-8.5%
Company:	(b)(4)							
Request:	0.005	0.060	75.000	520.000	2,200.000	3.000	981.000	Initial
Current Year MQ:	0.001	0.060	75.000	187.000	2,165.000	3.000	226.000	
Prev. Year's Sales:	-	-	-	112.015	1,197.382	0.011	20.614	
Total Prev. Year's Sales:	1,331.367	1,331.367	1,331.367	1,331.367	1,331.367	1,331.367	1,331.367	
% of Prev. Year's Sales:	0%	0%	0%	8%	90%	0%	2%	
Share of Next Year's PQs:	-	-	-	436.039	4,661.027	0.043	80.244	
Prev. Yr. Year-end Inv.:	-	0.208	-	30.110	638.030	1.171	11.536	
Proj. Exports Current Year:	-	-	-	-	24.900	-	-	
estimated current year sales:	0.001	0.007	58.000	356.000	2,001.120	3.500	300.000	
Proj. Exports Next Year:	-	-	-	-	24.900	-	-	
Company's Proj. Inv. Current Yr.:	0.001	0.214	17.000	146.608	640.327	0.600	11.900	
DEA's Proj. Inv. Current Year:	-	0.261	17.000	(138.890)	777.010	0.671	(62.464)	
INITIAL MQs								
2/3 calculation	0.001	0.179	50.000	144.740	1,868.687	2.781	158.357	
Calc. Using Company's Inv.:	(0.001)	(0.214)	(17.000)	507.450	6,376.114	(0.536)	108.466	
Calc. Using DEA's Inv.:	-	(0.261)	(17.000)	792.948	6,239.431	(0.607)	182.830	
Calc. using CFR 50% inventory	-	(0.261)	(17.000)	711.942	5,348.619	(0.615)	167.922	
Further Calculation:	0.005	0.060	75.000	520.000	2,200.000	3.000	226.000	
MQ:	0.005	0.060	75.000	520.000	2,200.000	3.000	226.000	
Total Initial MQs:	3,024.065	+ others		=	3,024.065			

FURTHER CALCULATIONS Initial

Update numbers below

		MQs 2010	2,741.061
		MQs 2011	3,779.765
		Final 2010	3,070.000
PQ * 1.5 - YE! =	7,180.29	**Initial APQ**	3,070.000
FDA est: APQ last year * est =	2809.05		

Initial MQs 2011

BASIC CLASS:	2011 Initial Quota Worksheets			9333																					
Company:	(b)(4)																								
Request:	2,663.000				3,500.000			Initial	40,000.000				24,000.000				11,000.000								
Current Year MQ:	416.000				30.000				43,000.000				23,500.000				8,048.000								
Prev. Yr. Year-end Inv.:	101.882				47.620				9,040.544				2,143.026				1,225.813								
Company's Proj. Inv. Current Yr.:	165.000				48.080				9,100.000				7,421.000				3,099.387								
Calculations	**amt. needed**	**substance**	**MQ**		**yield**	**amt. needed**	**substance**	**MQ**		**yield**	**amt. needed**	**substance**	**MQ**		**yield**	**amt. needed**	**substance**	**MQ**		**yield**	**amt. needed**	**substance**	**MQ**		**yield**	**yield**
(based on request)	0	oxycodone			67%	1,420.455	oxycodone	1,000.0		70%	30,000.000	oxycodone	24,000.0		80%	41,875.000	oxycodone	33,500.0		80%	0	oxycodone	-		83%	88%
	530	hydrocodon	281.0		53%																				
total need	530.189					1,420.455					30,000.000					41,875.000					-					
INITIAL MQs																									
2010/4+2011/4+2011-YEI 2010	661.736					1,734.868					39,150.000					50,797.750					(1,087.387)				
MQ:	662.000					1,735.000					40,000.000					24,000.000					-				
Total Initial MQs:	66,397.000	+ others	3.032	=		66,400.032															(supplies (b)(4)					
FURTHER CALCULATIONS																									
Update numbers below																									
							MQs 2010				104,497.030														
							MQs 2011				109,668.032														
							Final 2010				126,000.000														
applyig FDA est of Oxy to thebaine.	137340						Initial APQ			Initial	126,000.000														
oxycodone APQ =	105500																								
using (b)(4) rough approximation of thebaine needed = APQ/0.69						152,898.551																			
keep (b)(4) (oxycodone not changed)																									

Initial Aggregate Production Quotas for 2009

Oplates	2009 Initial Quota Worksheets				
Company (requests)	(b)(4)				
morphine for sale	32.000	2,218.000	17,000.000	13,432.000	362.000
morphine for conversion	-	2,950.000	44,000.000	16,997.000	5,110.800
total morphine	32.000	5,168.000	61,000.000	30,429.000	5,472.800
PQ opium for morphine	-	-	1,050.000	-	-
PQ CPS (AMA) for morphine	45.000	21,000.000	43,000.000	29,800.000	5,400.000
total morphine PQ	45.000	21,000.000	44,050.000	29,800.000	5,400.000
difference	(13.000)	(15,832.000)	16,950.000	629.000	72.800
thebaine	2,663.000	3,500.000	40,000.000	24,000.000	11,000.000
PQ CPS (ATA) for thebaine	3,875.000	14,000.000	39,000.000	65,200.000	10,500.000
difference	(1,212.000)	(10,500.000)	1,000.000	(41,200.000)	500.000
Company (grant)	(b)(4)				
morphine for sale	32.000	620.000	17,000.000	13,432.000	-
morphine for conversion	-	2,950.000	44,000.000	17,000.000	3,200.000
total morphine	32.000	3,570.000	61,000.000	30,432.000	3,200.000
PQ opium for morphine	-	-	1,050.000	-	-
PQ CPS (AMA) for morphine (need)	32.000	3,570.000	59,950.000	30,432.000	3,200.000
Grant					
thebaine (grant)	662.000	1,735.000	40,000.000	24,000.000	6,000.000
PQ CPS (ATA) for thebaine (need)					

2011 Proposed Initial Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, proposes initial year 2011 aggregate production quotas (APQ) for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2008, 2009 and 2010 APQs for these substances for comparison.

- Most of the proposed initial 2011 APQ values are recommended at the corresponding final 2010 aggregate levels.

Schedule I substances

- The small quantities listed for schedule I substances are manufactured mainly for use in analytical reference standards.

- Gamma hydroxybutyric acid (GHB) is used to manufacture Xyrem, a schedule III product used to treat narcolepsy. Xyrem is marketed by (b)(4) The GHB APQ was reduced because the main manufacturer (b)(4) is no longer manufacturing GHB. (b)(4) manufactured 2011 GHB requirements in 2010 and hence, why the final 2010 APQ was so large.

- Marihuana plant material is being grown by the National Center for the Development of Natural Products, associated with the University of Mississippi, for purposes of extracting tetrahydrocannabinol (THC) and other cannabinoids.

- Tetrahydrocannabinols (THC) is used to make the schedule III product Marinol and is also being used for the development of new products. The APQ for THC represents individual manufacturing quotas for synthetic THC.

Schedule II substances

- 4-anilino-N-phenethyl-4-piperidine (ANPP) became a schedule II controlled substance August 30, 2010. ANPP is used to manufacture fentanyl.

- Amphetamine (for conversion) is used to manufacture lisdexamfetamine.

- Codeine (for conversion) is used to manufacture hydrocodone, oxycodone, and dihydrocodeine.

- Morphine (for conversion) is used to manufacture codeine, dihydromorphine, hydromorphone and noroxymorphone.

- Noroxymorphone (for conversion) is used to manufacture various "nal" (narcotic antagonist) drugs, specifically naloxone and naltrexone.

- Oxycodone (for conversion) is used to manufactureoxymorphone.

- Oxymorphone (for conversion) is used to manufacture noroxymorphone (for conversion).

Attachment

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-343P]

Controlled Substances:
Proposed Aggregate Production Quotas for 2011

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed year 2011 aggregate production quotas.

SUMMARY: This notice proposes initial year 2011 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked and electronic comments must be submitted on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-343P" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments may be sent to DEA by sending an electronic message to dea.diversion.policy@usdoj.gov. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes. Commenters in time zones other

than Eastern Time may want to consider this so that their electronic comments are received timely. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (b)(6)

AVAILABILITY OF PUBLIC COMMENTS: Please note that all comments received are considered part of the public record and made available for public inspection in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a

comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. § 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR § 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR § 0.104.

The proposed year 2011 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2011 to provide adequate supplies of each substance for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the year 2011 aggregate production quotas, the Deputy Administrator considered the following factors: total actual 2009 and estimated 2010 and 2011 net disposals of each substance by all manufacturers; estimates of 2010 year-end inventories of each substance and of any substance manufactured from it and trends in accumulation of such inventories;

product development requirements of both bulk and finished dosage form manufacturers; projected demand as indicated by procurement quota applications filed pursuant to 21 CFR § 1303.12; and other pertinent information.

Pursuant to 21 CFR § 1303, the Deputy Administrator of the DEA will adjust the 2011 aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2010 year-end inventory and actual 2010 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA of 1970 (21 U.S.C. § 826), and delegated to the Administrator of the DEA by 28 CFR § 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR § 0.104, the Deputy Administrator hereby proposes that the year 2011 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Proposed 2011 Quotas
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	20 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g

Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	3 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	3 g
Gamma-hydroxybutyric acid	3,000,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	1 g
Lysergic acid diethylamide (LSD)	15 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	7 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g

Norlevorphanol	52 g
Normethadone	2 g
Normorphine	16 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	264,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Proposed 2011 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,500,000 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	40,003 g
Amphetamine (for conversion)	7,500,000 g
Amphetamine (for sale)	18,600,000 g
Cocaine	247,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	92,000,000 g
Dihydrocodeine	800,000 g
Diphenoxylate	827,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	55,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	11 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	9,000,000 g
Meperidine	6,600,000 g
Meperidine Intermediate-A	3 g

Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	1 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	9,002 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	41,000 g
Opium (powder)	230,000 g
Opium (tincture)	1,500,000 g
Oripavine	15,000,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	105,500,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	3,070,000 g
Pentobarbital	28,000,000 g
Phenazocine	1 g
Phencyclidine	14 g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	67,000 g
Sufentanil	7,000 g
Tapentadol	1,000,000 g
Thebaine	126,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR §§ 1308.11 and 1308.12 be established at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the "addresses" section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks.

While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $129,400,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated:

Michele M. Leonhart
Deputy Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODE:_____
ODE/D:(b)(6)_____
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2010 Initial APQ Comments

Drug	Company	Comment	Response	Proposed	Established	Change
3,4-methylenedioxyamphetamine (MDA)	(b)(4)	increase APQ	increase APQ	0.020	0.022	0.002
3,4-methylenedioxy-N-ethylamphetamine (MDEA)		increase APQ	increase APQ	0.010	0.015	0.005
3,4-methylenedioxymethamphetamine (MDMA)		increase APQ	increase APQ	0.020	0.022	0.002
4-anilino-N-phenethyl-4-piperidine (ANPP)		increase APQ	APQ adequate - no change	2,500.000	2,500.000	-
amphetamine		increase APQ	APQ adequate - no change	18,600.000	18,600.000	-
cathinone		increase APQ	increase APQ	0.003	0.004	0.001
codeine (for sale)		increase APQ	APQ adequate - no change	39,605.000	39,605.000	-
dihydromorphine		increase APQ	APQ adequate - no change	3,608.000	3,608.000	-
fentanyl		increase APQ	APQ adequate - no change	1,428.000	1,428.000	-
gamma hydroxybutryic acid		increase APQ increase APQ increase APQ increase APQ increase APQ	APQ adequate - no change	3,000.000	3,000.000	-
heroin		increase APQ	APQ adequate - no change	0.020	0.020	-
hydrocodone		increase APQ	APQ adequate - no change	55,000.000	55,000.000	-
hydromorophone		increase APQ	APQ adequate - no change	3,455.000	3,455.000	-
marihuana (cannabidiol, cannabinol)		increase APQ	APQ adequate - no change	21.000	21.000	-
meperidine		increase APQ	APQ adequate - no change	6,600.000	6,600.000	-
methaqualone		increase APQ	increase APQ	0.007	0.010	0.003
methylphenidate		increase APQ	APQ adequate - no change	50,000.000	50,000.000	-
morphine (for conversion)		increase APQ	APQ adequate - no change	83,000.000	83,000.000	-
morphine (for sale)		increase APQ increase APQ	APQ adequate - no change	39,000.000	39,000.000	-
nabilone		increase APQ	increase APQ - additional exports	9.002	10.502	1.500
noroxymorphone (for conversion)		increase APQ	APQ adequate - no change	9,000.000	9,000.000	-
opium (tincture)		increase APQ	APQ adequate - no change	1,500.000	1,500.000	-
oxycodone (for sale)		increase APQ	APQ adequate - no change	105,500.000	105,500.000	-
pentobarbital		increase APQ	APQ adequate - no change	28,000.000	28,000.000	-
phencyclidine		increase APQ	increase APQ	0.014	0.024	0.010
remifentanil		increase APQ	APQ adequate - no change	2.500	2.500	-
secobarbital		increase APQ	increase APQ	67.000	260.002	193.002
tapentadol		increase APQ	APQ adequate - no change	1,000.000	1,000.000	-
tetrahydrocannabinols		increase APQ	increase APQ	264.000	393.000	129.000
thebaine		increase APQ increase APQ	APQ adequate - no change	126,000.000	126,000.000	-
tilidine		increase APQ	APQ adequate - no change	0.010	0.010	-

Number of Companies commenting: 7 (one non-registrant); (one registrant that is surrendering registration)
Number of drugs commented on: 31

Additional Changes:

Drug	Response	Proposed	Established	Change

amobarbital	additional applications received	40.003	40.007	0.004
dimethyltriptamine	additional applications received	0.003	0.007	0.004
ibogaine	additional applications received	0.001	0.005	0.004
lysergic acid diethylamide	additional applications received	0.015	0.016	0.001
metazocine	additional applications received	0.001	0.005	0.004
normorphine	additional applications received	0.016	0.018	0.002
noroxymorphone (for sale)	additional applications received	41.000	401.000	360.000
phenazocine	additional applications received	0.001	0.005	0.004

2011 Establish Initial Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, established initial year 2011 aggregate production quotas (APQ) for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2009 and proposed 2010 APQs for these substances for comparison.

- Expeditious publication of this notice is necessary to ensure that quota is available at the beginning of 2011 for manufacturing. The following points provide brief explanations of the changes from the proposed APQ values:

Schedule I substances

- The APQ for **3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxy-N-ethylamphetamine (MDEA), 3,4-methylenedioxymethamphetamine (MDMA), cathinone,** and **methaqualone,** were increased due to additional requirements for diagnostic kits and or reference standards.

- The APQ for **dimethyltryptamine, ibogaine, lysergic acid diethylamide,** and **normorphine** were increased due to additional applications received to support the manufacturing of diagnostic kits and or reference standards.

- The APQ for **gamma hydroxybutyric acid (GHB)** was not increased. Due to the closing of (b)(4) the sole provider of GHB to (b)(4) Xyrem® contract manufacturer (b)(4) the 2010 APQ was increased to provide enough GHB to supply (b)(4) through 2011. As such, the 2011 GHB was subsequently proposed at a much lower value than the previous year and despite comments to increase the APQ, DEA is establishing the initial 2011 APQ at the proposed value. This may result in multiple inquiries or letters to the Administrator from (b)(4) or their contract manufacturers (b)(4)

- The APQ for **tetrahydrocannabinols** was increased to support the manufacturing of ajulemic acid (a tetrahydrocannabinol derivative) and additional process development/research.

Schedule II substances

- The APQ for **phencyclidine** was increased due to additional requirements for diagnostic kits and or reference standards.

- The APQ for **amobarbital, metazocine,** and **phenazocine** were increased due to additional applications received to support the manufacturing of diagnostic kits and or reference standards.

- The APQ for **nabilone** was increased to support increased exportation requirements.

- The APQ for **noroxymorphone (for sale)** was increased to support new manufacturing of NKTR-118, or mPEG-Naloxol which falls under the basic drug class noroxymorphone.

- The APQ for **secobarbital** was increased to support validation efforts of (b)(4)

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA # 343E]

Controlled Substances:
Established Initial Aggregate Production Quotas for 2011

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2011.

SUMMARY: This notice establishes initial 2011 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: (insert date of publication).

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (b)(6)

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. § 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR § 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR § 0.104.

The 2011 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2011 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful

export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. § 826(a) and 21 CFR § 1303.11). These quotas do not include imports of controlled substances for use in industrial processes.

On September 15, 2010, a notice of the proposed initial 2011 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (75 FR 56137). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before October 15, 2010.

Seven responses (six from DEA registered manufacturers, and one from a non-DEA registrant) were received within the published comment period, offering comments on a total of 31 schedule I and II controlled substances. The commenters stated that the proposed aggregate production quotas for 3,4-methylenedioxyamphetamine, 3,4-methylenedioxy-N-ethylamphetamine, 3,4-methylenedioxymethamphetamine, 4-anilino-N-phenethyl-4-piperidine, amphetamine (for sale), cathinone, codeine (for sale), dihydromorphine, fentanyl, gamma hydroxybutyric acid, heroin, hydrocodone, hydromorphone, marihuana, meperidine, methaqualone, methylphenidate, morphine (for conversion), morphine (for sale), nabilone, noroxymorphone (for conversion), opium (tincture), oxycodone (for sale), pentobarbital, phencyclidine, remifentanil, secobarbital, tapentadol, tetrahydrocannabinols, thebaine and tilidine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

In arriving at the aggregate production quotas, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR § 1303.11(b) and other relevant 2010

factors, including 2010 manufacturing quotas, current 2010 sales and inventories, 2011 export requirements, additional applications received, as well as research and product development requirements. Based on this information, DEA has adjusted the initial aggregate production quotas for 3,4-methylenedioxyamphetamine, 3,4-methylenedioxy-N-ethylamphetamine, 3,4-methylenedioxymethamphetamine, amobarbital, cathinone, dimethyltryptamine, ibogaine, lysergic acid diethylamide, metazocine, methaqualone, nabilone, normorphine, noroxymorphone (for sale), phenazocine, phencyclidine, secobarbital, and tetrahydrocannabinols to meet the legitimate needs of the United States.

Regarding 4-anilino-N-phenethyl-4-piperidine, amphetamine (for sale), codeine (for sale), dihydromorphine, fentanyl, gamma hydroxybutyric acid, heroin, hydrocodone, hydromorphone, marihuana, meperidine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), opium (tincture), oxycodone (for sale), pentobarbital, remifentanil, tapentadol, thebaine and tilidine DEA has determined that the proposed initial 2011 aggregate production quotas are sufficient to meet the current 2011 estimated medical, scientific, research and industrial needs of the United States.

Pursuant to 21 CFR § 1303, the Deputy Administrator of DEA will, in 2011, adjust aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2010 year-end inventory and actual 2010 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. § 826), and delegated to the Administrator of DEA by 28 CFR § 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR § 0.104, the Deputy Administrator

hereby orders that the 2011 initial aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Established 2011 Quotas
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g

Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	3,000,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2011 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g

4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,500,000 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	7,500,000 g
Amphetamine (for sale)	18,600,000 g
Cocaine	247,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	92,000,000 g
Dihydrocodeine	800,000 g
Diphenoxylate	827,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	55,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	11 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	9,000,000 g
Meperidine	6,600,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	10,502 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	401,000 g
Opium (powder)	230,000 g

Opium (tincture)	1,500,000 g
Oripavine	15,000,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	105,500,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	3,070,000 g
Pentobarbital	28,000,000 g
Phenazocine	5 g
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	260,002 g
Sufentanil	7,000 g
Tapentadol	1,000,000 g
Thebaine	126,000,000 g

The Deputy Administrator further orders that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR §§ 1308.11 and 1308.12 be established at zero.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are

necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $126,400,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated:

Michele M. Leonhart
Deputy Administrator

Aggregate Production Quota Changes

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Final Revised	Proposed Initial	Initial	Proposed Revised
Schedule I:	**2009**	**2010**	**2011**	**2011**	**2011**
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	0	0	0	0	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	0	0	0	0	45
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	0	0	0	0	45
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	0	0	0	0	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	0	0	0	0	53
Difenoxin	3,000	3,000	3,000	3,000	50
Gamma-hydroxybutyric acid	24,200,000	52,156,000	3,000,000	3,000,000	5,434,000
	Final Revised	**Final Revised**	**Proposed Initial**	**Initial**	**Proposed Revised**
Schedule II:	**2009**	**2010**	**2011**	**2011**	**2011**
4-Anilino-N-phenethyl-4-piperidine (ANPP)	0	1,100,000	2,500,000	2,500,000	1,800,000
Alfentanil	8,000	8,000	8,000	8,000	11,600
Amphetamine (for conversion)	7,500,000	7,500,000	7,500,000	7,500,000	8,500,000
Amphetamine (for sale)	17,000,000	18,600,000	18,600,000	18,600,000	25,300,000
Cocaine	247,000	247,000	247,000	247,000	216,000
Dextropropoxyphene	106,000,000	92,000,000	92,000,000	92,000,000	7
Dihydrocodeine	1,200,000	800,000	800,000	800,000	255,000
Diphenoxylate	947,000	827,000	827,000	827,000	500,000
Hydrocodone (for sale)	55,500,000	55,000,000	55,000,000	55,000,000	59,000,000
Isomethadone	2	11	11	11	2
Levomethorphan	5	5	5	5	2
Levorphanol	10,000	10,000	10,000	10,000	3,600
Lisdexamfetamine	8,200,000	9,000,000	9,000,000	9,000,000	10,400,000
Meperidine	8,600,000	6,600,000	6,600,000	6,600,000	5,200,000
Methylphenidate	50,000,000	50,000,000	50,000,000	50,000,000	56,000,000
Morphine (for conversion)	100,000,000	83,000,000	83,000,000	83,000,000	70,000,000
Noroxymorphone (for conversion)	9,000,000	9,000,000	9,000,000	9,000,000	7,200,000
Opium (powdered)	230,000	230,000	230,000	230,000	63,000
Opium (tincture)	1,250,000	1,500,000	1,500,000	1,500,000	1,000,000
Oripavine	15,000,000	15,000,000	15,000,000	15,000,000	8,000,000
Oxycodone (for sale)	94,000,000	105,500,000	105,500,000	105,500,000	98,000,000
Oxymorphone (for sale)	2,570,000	3,070,000	3,070,000	3,070,000	3,370,000
Pentobarbital	28,000,000	28,000,000	28,000,000	28,000,000	31,000,000
Secobarbital	67,000	67,000	67,000	260,002	336,002
Sufentanil	10,300	7,000	7,000	7,000	5,000
Tapentadol	0	1,000,000	1,000,000	1,000,000	403,000
Thebaine	126,000,000	126,000,000	126,000,000	126,000,000	116,000,000

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-343R]

Controlled Substances:
Proposed Adjustment to the Aggregate Production Quotas for 2011 and Proposed Initial Aggregate Production Quotas for 2011 for Temporarily Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2011 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA) and separately proposes to establish aggregate production quotas for five synthetic cannabinoids temporarily controlled in Schedule I.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-343R" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov website for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish

to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, UN Reporting and Quota Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (b)(6)

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot

be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. On September 15, 2010, a notice of proposed 2011 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (75 FR 56137). That notice stipulated that the Administrator would adjust, as needed, the quotas in 2011 as provided for in 21 CFR 1303.13. The 2011 established aggregate production quotas were subsequently published in the Federal Register (75 FR 79404) on December 20, 2010.

Additionally, on March 1, 2011, the DEA Administrator published a Final Order which temporarily placed five synthetic cannabinoids in schedule I: 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200); 1-Butyl-3-(1-naphthoyl)indole (JWH-073); 1-Pentyl-3-(1-naphthoyl)indole (JWH-018); 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497); and 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue) (76 FR 11075). That Final Order stated that quotas for the five substances would be "established based on registrations granted and quota

applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations." 76 FR 11075. Aggregate productions quotas for these temporarily scheduled substances have not previously been established.

Analysis for Proposed Revised 2011 Aggregate Production Quotas

DEA now proposes to adjust the established 2011 aggregate production quotas for some schedule I and II controlled substances. In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13. DEA proposes the adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances by considering (1) changes in demand for the class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand can be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant.

In determining whether to propose adjustments to the 2011 aggregate production quotas, DEA considered updated information obtained from 2010 year-end inventories, 2010 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas had been established. The Administrator, therefore, proposes to adjust the 2011 aggregate

production quotas for some schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

Basic Class – schedule I	Previously Established Initial 2011 Quotas	Proposed Adjusted 2011 Quotas
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No Change
2,5-Dimethoxyamphetamine	2 g	No Change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	No Change
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g	No Change
3-Methylfentanyl	2 g	No Change
3-Methylthiofentanyl	2 g	No Change
3,4-Methylenedioxyamphetamine (MDA)	22 g	No Change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g	No Change
3,4-Methylenedioxymethamphetamine (MDMA)	22 g	No Change
3,4,5-Trimethoxyamphetamine	2 g	No Change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	No Change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	No Change
4-Methoxyamphetamine	77 g	No Change
4-Methylaminorex	2 g	No Change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	No Change
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	No Change
5-Methoxy-N,N-diisopropyltryptamine	2 g	No Change
Acetyl-alpha-methylfentanyl	2 g	No Change
Acetyldihydrocodeine	2 g	No Change
Acetylmethadol	2 g	No Change
Allylprodine	2 g	No Change
Alphacetylmethadol	2 g	No Change
Alpha-ethyltryptamine	2 g	No Change
Alphameprodine	2 g	No Change
Alphamethadol	2 g	No Change
Alpha-methylfentanyl	2 g	No Change
Alpha-methylthiofentanyl	2 g	No Change
Alpha-methyltryptamine (AMT)	2 g	No Change
Aminorex	2 g	No Change
Benzylmorphine	2 g	No Change
Betacetylmethadol	2 g	No Change
Beta-hydroxy-3-methylfentanyl	2 g	No Change
Beta-hydroxyfentanyl	2 g	No Change
Betameprodine	2 g	No Change
Betamethadol	2 g	No Change

Betaprodine	2 g	No Change
Bufotenine	3 g	No Change
Cathinone	4 g	No Change
Codeine-N-oxide	602 g	No Change
Diethyltryptamine	2 g	No Change
Difenoxin	3,000 g	50 g
Dihydromorphine	3,608,000 g	No Change
Dimethyltryptamine	7 g	No Change
Gamma-hydroxybutyric acid	3,000,000 g	5,434,000 g
Heroin	20 g	No Change
Hydromorphinol	2 g	No Change
Hydroxypethidine	2 g	No Change
Ibogaine	5 g	No Change
Lysergic acid diethylamide (LSD)	16 g	No Change
Marihuana	21,000 g	No Change
Mescaline	5 g	No Change
Methaqualone	10 g	No Change
Methcathinone	4 g	No Change
Methyldihydromorphine	2 g	No Change
Morphine-N-oxide	605 g	No Change
N-Benzylpiperazine	2 g	No Change
N,N-Dimethylamphetamine	2 g	No Change
N-Ethylamphetamine	2 g	No Change
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	No Change
Noracymethadol	2 g	No Change
Norlevorphanol	52 g	No Change
Normethadone	2 g	No Change
Normorphine	18 g	No Change
Para-fluorofentanyl	2 g	No Change
Phenomorphan	2 g	No Change
Pholcodine	2 g	No Change
Psilocybin	2 g	No Change
Psilocyn	2 g	No Change
Tetrahydrocannabinols	393,000 g	No Change
Thiofentanyl	2 g	No Change
Tilidine	10 g	No Change
Trimeperidine	2 g	No Change

Basic Class – schedule II	Previously Established Initial 2011 Quotas	Proposed Adjusted 2011 Quotas
1-Phenylcyclohexylamine	2 g	No Change
1-Piperdinocyclohexanecarbonitrile	2 g	No Change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,500,000 g	1,800,000 g
Alfentanil	8,000 g	11,600 g
Alphaprodine	2 g	No Change
Amobarbital	40,007 g	No Change
Amphetamine (for conversion)	7,500,000 g	8,500,000 g
Amphetamine (for sale)	18,600,000 g	25,300,000 g
Cocaine	247,000 g	216,000 g
Codeine (for conversion)	65,000,000 g	No Change
Codeine (for sale)	39,605,000 g	No Change
Dextropropoxyphene	92,000,000 g	7 g
Dihydrocodeine	800,000 g	255,000 g
Diphenoxylate	827,000 g	500,000 g
Ecgonine	83,000 g	No Change
Ethylmorphine	2 g	No Change
Fentanyl	1,428,000 g	No Change
Glutethimide	2 g	No Change
Hydrocodone (for sale)	55,000,000 g	59,000,000 g
Hydromorphone	3,455,000 g	No Change
Isomethadone	11 g	2 g
Levo-alphacetylmethadol (LAAM)	3 g	No Change
Levomethorphan	5 g	2 g
Levorphanol	10,000 g	3,600 g
Lisdexamfetamine	9,000,000 g	10,400,000 g
Meperidine	6,600,000 g	5,200,000 g
Meperidine Intermediate-A	3 g	No Change
Meperidine Intermediate-B	7 g	No Change
Meperidine Intermediate-C	3 g	No Change
Metazocine	5 g	No Change
Methadone (for sale)	20,000,000 g	No Change
Methadone Intermediate	26,000,000 g	No Change
Methamphetamine	3,130,000 g	No Change
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	50,000,000 g	56,000,000 g
Morphine (for conversion)	83,000,000 g	70,000,000 g

Morphine (for sale)	39,000,000 g	No Change
Nabilone	10,502 g	No Change
Noroxymorphone (for conversion)	9,000,000 g	7,200,000 g
Noroxymorphone (for sale)	401,000 g	No Change
Opium (powder)	230,000 g	63,000 g
Opium (tincture)	1,500,000 g	1,000,000 g
Oripavine	15,000,000 g	8,000,000 g
Oxycodone (for conversion)	5,600,000 g	No Change
Oxycodone (for sale)	105,500,000 g	98,000,000 g
Oxymorphone (for conversion)	12,800,000 g	No Change
Oxymorphone (for sale)	3,070,000 g	No Change
Pentobarbital	28,000,000 g	31,000,000 g
Phenazocine	5 g	No Change
Phencyclidine	24 g	No Change
Phenmetrazine	2 g	No Change
Phenylacetone	8,000,000 g	No Change
Racemethorphan	2 g	No Change
Remifentanil	2,500 g	No Change
Secobarbital	260,002 g	336,002 g
Sufentanil	7,000 g	5,000 g
Tapentadol	1,000,000 g	403,000 g
Thebaine	126,000,000 g	116,000,000 g

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Analysis for Proposed Aggregate Production Quotas for Temporarily Scheduled Substances

The proposed year 2011 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2011 to provide adequate supplies of each substance for estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the year 2011 aggregate production quotas for the five temporarily scheduled controlled substances listed below, the Administrator considered the following factors, in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11: total estimated net disposal of each substance by all manufacturers; total estimated inventories of the class and of all substances manufactured in the class; projected demand for such class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements.

DEA has received applications for registration and quota for the temporarily scheduled controlled substances listed below. In examining the information provided by the applicant(s), along with other information, DEA finds that there is a current need for these substances. The Administrator therefore proposes that the year 2011 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – schedule I	Proposed 2011 Quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497)	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue)	53 g

Pursuant to 21 CFR Part 1303, the Administrator may adjust the 2011 aggregate production quotas and individual manufacturing quotas allocated for the year.

Comments

Pursuant to 21 CFR 1303.11 and 1303.13, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the Federal Register a Final Order determining any adjustment of the aggregate production quota.

_____
Date

_____
Michele M. Leonhart
Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODQ:_____
ODQ:(b)(6) _____
ODQMTD: _____(b)(6)
Webcims #
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

2011 Proposed Revised Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, Proposed Revised Aggregate Production Quotas (APQ) for 2011 for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export, and reserve stock requirements. Also attached is a list of the 2009 and 2010 APQs for these substances for comparison.

- An expedited review and publication is requested to ensure an uninterruptable supply of schedule I and II controlled substances for medical, scientific, industrial, and export requirements of the U.S.

- The following points provide brief explanations of the changes from the proposed APQ values:

Schedule I substances

- The APQ difenoxin was decreased.

- The APQ for 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 1-Butyl-3-(1-naphthoyl)indole (JWH-073), 1-Pentyl-3-(1-naphthoyl)indole (JWH-018), 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol, and 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol were established. They are five of the synthetic cannabinoids found in the "Spice" products which were temporary placed in schedule I, March 1, 2011 (76 FR 11075). The manufacturing of these substances will be used for analytical standards, reference and research material.

- The APQ for gamma-hydroxybutyric acid (GHB) was increased to support validation efforts. (b)(4) is validating two new suppliers of gamma-butyrolactone, a list I chemical used to manufacture GHB.

Schedule II substances

- The APQ for 4-anilino-N-pheneythl-4-piperidine (ANPP), cocaine, dextropropoxyphene, dihydrocodeine, diphenoxylate, isomethadone, levomethorphan, levorphanol, meperidine, morphine (for conversion), noroxymorphone (for conversion), opium (powdered), opium (tincture), oripavine, oxycodone (for sale), sufentanil, tapentadol, and thebaine were decreased.

- The APQ for alfentanil was increased due to increased exportation requirements.

- The APQ for lisdexamfetamine, methylphenidate, and oxymorphone (for sale) were increased due to increased sales. Since amphetamine (for conversion) is used to manufacture lisdexamfetamine, the APQ for amphetamine (for conversion) was subsequently increased.

- The APQ for amphetamine (for sale) was increased due to increased sales and to support the validation efforts of two new bulk manufacturers (b)(4) Amphetamine manufacturing has high losses due to the isomer isolation, i.e., d-amphetamine from the racemic (d,l-amphetamine) mixture.

- The APQ for hydrocodone was increased due to increased sales. This is likely due to FDA removing dextropropoxyphene from the market, and FDA identifying hydrocodone as one of the recommended replacement substances.

- The APQ for pentobarbital was increased because (b)(4) now properly assesses their quota at the initial manufacturing stage vs. the final finished product. The increase is accounting for their manufacturing losses.

- The APQ for secobarbital was increased to support additional validation batches (b)(4) prior batches failed and they need to manufacture additional material to support FDA requirements).

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-343R]

Controlled Substances:
Proposed Adjustment to the Aggregate Production Quotas for 2011 and Proposed Initial Aggregate Production Quotas for 2011 for Temporarily Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2011 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA) and separately proposes to establish aggregate production quotas for five synthetic cannabinoids temporarily controlled in Schedule I.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-343R" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov website for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish

to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, UN Reporting and Quota Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-7184.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot

be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. On September 15, 2010, a notice of proposed 2011 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (75 FR 56137). That notice stipulated that the Administrator would adjust, as needed, the quotas in 2011 as provided for in 21 CFR 1303.13. The 2011 established aggregate production quotas were subsequently published in the Federal Register (75 FR 79404) on December 20, 2010.

Additionally, on March 1, 2011, the DEA Administrator published a Final Order which temporarily placed five synthetic cannabinoids in schedule I: 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200); 1-Butyl-3-(1-naphthoyl)indole (JWH-073); 1-Pentyl-3-(1-naphthoyl)indole (JWH-018); 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497); and 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue) (76 FR 11075). That Final Order stated that quotas for the five substances would be "established based on registrations granted and quota

applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations." 76 FR 11075. Aggregate productions quotas for these temporarily scheduled substances have not previously been established.

Analysis for Proposed Revised 2011 Aggregate Production Quotas

DEA now proposes to adjust the established 2011 aggregate production quotas for some schedule I and II controlled substances. In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13. DEA proposes the adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances by considering (1) changes in demand for the class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand can be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant.

In determining whether to propose adjustments to the 2011 aggregate production quotas, DEA considered updated information obtained from 2010 year-end inventories, 2010 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas had been established. The Administrator, therefore, proposes to adjust the 2011 aggregate

production quotas for some schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

Basic Class – schedule I	Previously Established Initial 2011 Quotas	Proposed Adjusted 2011 Quotas
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No Change
2,5-Dimethoxyamphetamine	2 g	No Change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	No Change
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g	No Change
3-Methylfentanyl	2 g	No Change
3-Methylthiofentanyl	2 g	No Change
3,4-Methylenedioxyamphetamine (MDA)	22 g	No Change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g	No Change
3,4-Methylenedioxymethamphetamine (MDMA)	22 g	No Change
3,4,5-Trimethoxyamphetamine	2 g	No Change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	No Change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	No Change
4-Methoxyamphetamine	77 g	No Change
4-Methylaminorex	2 g	No Change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	No Change
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	No Change
5-Methoxy-N,N-diisopropyltryptamine	2 g	No Change
Acetyl-alpha-methylfentanyl	2 g	No Change
Acetyldihydrocodeine	2 g	No Change
Acetylmethadol	2 g	No Change
Allylprodine	2 g	No Change
Alphacetylmethadol	2 g	No Change
Alpha-ethyltryptamine	2 g	No Change
Alphameprodine	2 g	No Change
Alphamethadol	2 g	No Change
Alpha-methylfentanyl	2 g	No Change
Alpha-methylthiofentanyl	2 g	No Change
Alpha-methyltryptamine (AMT)	2 g	No Change
Aminorex	2 g	No Change
Benzylmorphine	2 g	No Change
Betacetylmethadol	2 g	No Change
Beta-hydroxy-3-methylfentanyl	2 g	No Change
Beta-hydroxyfentanyl	2 g	No Change
Betameprodine	2 g	No Change
Betamethadol	2 g	No Change

Betaprodine	2 g	No Change
Bufotenine	3 g	No Change
Cathinone	4 g	No Change
Codeine-N-oxide	602 g	No Change
Diethyltryptamine	2 g	No Change
Difenoxin	3,000 g	50 g
Dihydromorphine	3,608,000 g	No Change
Dimethyltryptamine	7 g	No Change
Gamma-hydroxybutyric acid	3,000,000 g	5,434,000 g
Heroin	20 g	No Change
Hydromorphinol	2 g	No Change
Hydroxypethidine	2 g	No Change
Ibogaine	5 g	No Change
Lysergic acid diethylamide (LSD)	16 g	No Change
Marihuana	21,000 g	No Change
Mescaline	5 g	No Change
Methaqualone	10 g	No Change
Methcathinone	4 g	No Change
Methyldihydromorphine	2 g	No Change
Morphine-N-oxide	605 g	No Change
N-Benzylpiperazine	2 g	No Change
N,N-Dimethylamphetamine	2 g	No Change
N-Ethylamphetamine	2 g	No Change
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	No Change
Noracymethadol	2 g	No Change
Norlevorphanol	52 g	No Change
Normethadone	2 g	No Change
Normorphine	18 g	No Change
Para-fluorofentanyl	2 g	No Change
Phenomorphan	2 g	No Change
Pholcodine	2 g	No Change
Psilocybin	2 g	No Change
Psilocyn	2 g	No Change
Tetrahydrocannabinols	393,000 g	No Change
Thiofentanyl	2 g	No Change
Tilidine	10 g	No Change
Trimeperidine	2 g	No Change

Basic Class – schedule II	Previously Established Initial 2011 Quotas	Proposed Adjusted 2011 Quotas
1-Phenylcyclohexylamine	2 g	No Change
1-Piperdinocyclohexanecarbonitrile	2 g	No Change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,500,000 g	1,800,000 g
Alfentanil	8,000 g	11,600 g
Alphaprodine	2 g	No Change
Amobarbital	40,007 g	No Change
Amphetamine (for conversion)	7,500,000 g	8,500,000 g
Amphetamine (for sale)	18,600,000 g	25,300,000 g
Cocaine	247,000 g	216,000 g
Codeine (for conversion)	65,000,000 g	No Change
Codeine (for sale)	39,605,000 g	No Change
Dextropropoxyphene	92,000,000 g	7 g
Dihydrocodeine	800,000 g	255,000 g
Diphenoxylate	827,000 g	500,000 g
Ecgonine	83,000 g	No Change
Ethylmorphine	2 g	No Change
Fentanyl	1,428,000 g	No Change
Glutethimide	2 g	No Change
Hydrocodone (for sale)	55,000,000 g	59,000,000 g
Hydromorphone	3,455,000 g	No Change
Isomethadone	11 g	2 g
Levo-alphacetylmethadol (LAAM)	3 g	No Change
Levomethorphan	5 g	2 g
Levorphanol	10,000 g	3,600 g
Lisdexamfetamine	9,000,000 g	10,400,000 g
Meperidine	6,600,000 g	5,200,000 g
Meperidine Intermediate-A	3 g	No Change
Meperidine Intermediate-B	7 g	No Change
Meperidine Intermediate-C	3 g	No Change
Metazocine	5 g	No Change
Methadone (for sale)	20,000,000 g	No Change
Methadone Intermediate	26,000,000 g	No Change
Methamphetamine	3,130,000 g	No Change
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	50,000,000 g	56,000,000 g
Morphine (for conversion)	83,000,000 g	70,000,000 g

Morphine (for sale)	39,000,000 g	No Change
Nabilone	10,502 g	No Change
Noroxymorphone (for conversion)	9,000,000 g	7,200,000 g
Noroxymorphone (for sale)	401,000 g	No Change
Opium (powder)	230,000 g	63,000 g
Opium (tincture)	1,500,000 g	1,000,000 g
Oripavine	15,000,000 g	8,000,000 g
Oxycodone (for conversion)	5,600,000 g	No Change
Oxycodone (for sale)	105,500,000 g	98,000,000 g
Oxymorphone (for conversion)	12,800,000 g	No Change
Oxymorphone (for sale)	3,070,000 g	No Change
Pentobarbital	28,000,000 g	31,000,000 g
Phenazocine	5 g	No Change
Phencyclidine	24 g	No Change
Phenmetrazine	2 g	No Change
Phenylacetone	8,000,000 g	No Change
Racemethorphan	2 g	No Change
Remifentanil	2,500 g	No Change
Secobarbital	260,002 g	336,002 g
Sufentanil	7,000 g	5,000 g
Tapentadol	1,000,000 g	403,000 g
Thebaine	126,000,000 g	116,000,000 g

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Analysis for Proposed Aggregate Production Quotas for Temporarily Scheduled Substances

The proposed year 2011 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2011 to provide adequate supplies of each substance for estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the year 2011 aggregate production quotas for the five temporarily scheduled controlled substances listed below, the Administrator considered the following factors, in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11: total estimated net disposal of each substance by all manufacturers; total estimated inventories of the class and of all substances manufactured in the class; projected demand for such class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements.

DEA has received applications for registration and quota for the temporarily scheduled controlled substances listed below. In examining the information provided by the applicant(s), along with other information, DEA finds that there is a current need for these substances. The Administrator therefore proposes that the year 2011 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – schedule I	Proposed 2011 Quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497)	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue)	53 g

Pursuant to 21 CFR Part 1303, the Administrator may adjust the 2011 aggregate production quotas and individual manufacturing quotas allocated for the year.

Comments

Pursuant to 21 CFR 1303.11 and 1303.13, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the Federal Register a Final Order determining any adjustment of the aggregate production quota.

_____
Date

_____
Michele M. Leonhart
Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODQ:_____
ODQ:(b)(6) _____
ODQ(b)(6)
Webcims #
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

BASIC CLASS:	2011 Revised Quota Worksheets			9050 Codeine			
PQ Total:	25,788.381	kg					FDA Est.: -2.80%
							IMS: 17.8%
Company:	(b)(4)						
Request:	10.000	128.000	327.000	16,300.000	20,060.000	5,600.000	
Current Year MQ:	10.000	92.000	327.000	16,300.000	15,700.000	2,540.000	
Prev. Year's Sales:	-	-	33.300	13,406.378	11,018.199	1,546.871	
Total Prev. Year's Sales:	26,004.865	26,004.865	26,004.865	26,004.865	26,004.865	26,004.865	
% of Prev. Year's Sales:	0%	0%	0%	52%	42%	6%	
Share of current Year's PQs:	-	-	33.023	13,294.773	10,926.475	1,533.994	
Prev. Yr. Year-end Inv.:	-	-	386.249	3,823.833	7,051.794	1,125.397	
Proj. Exports Current Year:	-		-	740.000	-	-	
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	-	(336.715)	16,858.327	9,337.919	1,175.594	
Calucations w/ CFR 50%	-	-	(336.646)	16,886.228	9,360.850	1,178.813	
Further Calculation:							
Final MQ:	10.000	92.000	327.000	16,421.000	16,837.000	2,540.000	
Total revised MQs:	36,227.000		+ others	3.105	=	36,230.105	

FURTHER CALCULATIONS

						Initial
current PQ	25,788.381				Initial APQ	39,605.000
Current MQ	38,619.105				Proposed revised APQ	39,605.000
inventory	12,388.505				Final Revised APQ	39,605.000
MQ need = PQx1.5-MQ-inventory	(12,325.039)		CFR 50% rule	(12,431.314)		
last years APQ	39,605.000					
FDA est = APQ x est	38,496.060					
IMS est = APQ x est	46,654.690					

BASIC CLASS:	2011 Revised Quota Worksheets			9050 Codeine (for conversion)											
Company:	(b)(4)														
Request:	96.000			1,946.000			19,400.000			3,599.175			30,000.000		
Current Year MQ:	-			484.000			11,000.000			3,600.000			30,000.000		
Year end inventory	-			-			4,281.4780			-			7,565.4700		
Calculations	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	subtance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild
hydrocodone	#DIV/0!	-		331	281.000	0.850	5,140.845	3,650.000	0.710	#DIV/0!			23,913.043	22,000.000	0.920
dihydrocodeine										#DIV/0!			304.878	250.000	0.820
codeine for sale							344.211	327.000	0.950						
hydromorphone															
oxycodone									0.630						
TOTAL NEED:	#DIV/0!			331			5,485.056			#DIV/0!			24,217.922		
Revised MQ															
total x 50% inventory - YEI	#DIV/0!			495.882			3,946.105			#DIV/0!			28,761.412		
previous year MQ	0.000			280.000			14,000.000			-			7,565.470		
CFR 50% calculation	#DIV/0!			483.235294			6074.841496			#DIV/0!			24598.2994		
Final MQ	-			484.000			11,000.000			3,600.000			30,000.000		
Total revised MQs:	45,084.00	+ others					=	45,084.000							

FURTHER CALCULATIONS

(b)(4) new registration validation efforts / new process (b)(4) facility purchased)

Initial APQ	65,000.000
Proposed Final APQ	
Final Revised APQ	

BASIC CLASS:	2011 Revised Quota Worksheets		9801 Fentanyl					
PQ Total:	3,310.359						FDA Est.:	1.30%
							IMS est:	4.30%
Company:	(b)(4)							
Request:	0.005	3.2	268	200	0.002	52	300	610
Current Year MQ:	0.005	3.2	45	70	0.002	8	300	810
Prev. Year's Sales:	0	0	43.734	19.074	-	3.103	332.405	512.740
Total Prev. Year's Sales:	911	911	911.056	911.056	911.056	911.056	911.056	911.056
% of Prev. Year's Sales:	0%	0%	5%	2%	0%	0%	36%	56%
Share of current Year's PQs:	0	0	158.909	69.306	-	11.275	1,207.807	1,863.062
Prev. Yr. Year-end Inv.:	0	0	75.650	11.098	-	1.495	618.835	357.729
Proj. Exports Current Year:	0		22.400	50.000	-	2.000	-	101.000
Revised MQs' share PQ x 1.3 - YEI + exports								
Typcial calculation	0.000	0.000	153.332	129.000	0.000	15.162	951.314	2165.251
calculation with 50% CFR	0.000	0.000	156.320	130.303	0.000	15.374	974.025	2200.283
Further Calculation:								
Final MQ:	0.005	3.200	45.000	75.000	0.002	8.000	300.000	670.000
Total revised MQs:	1101 + others		-	=	1,101.207			

FURTHER CALCULATIONS

						Initial
current PQ	3,310.359				Initial APQ	1,428.000
Current MQ	1,236.207				proposed revised APQ	1,428.000
Inventory	1,064.807				Final Revised APQ	1,428.000
MQ need = PQx1.3-MQ-inventory	2,002.453		CFR 50%	2,064.699		
last year APQ	1,428.000					
FDA est = APQ x est	1,446.564					
IMS est = APQ x est	1,489.404					

BASIC CLASS:	2011 Revised Quota Worksheet		9193 Hydrocodone				
PQ Total:	76,134.014					FDA est:	6.80%
						IMS est:	5.60%
Company:	(b)(4)						
Request:	100	1,763.000	9,295.000	23,000.000	24,900.000	3,300.000	10,500.000
Current Year MQ:	0	281.000	3,650.000	22,000.000	23,400.000	1,500.000	3,800.000
Prev. Year's Sales:	-	58.965	3,212.293	17,851.648	17,044.303	243.072	2,579.806
Total Prev. Year's Sales:	41,165.862	41,165.862	41,165.862	41,165.862	41,165.862	41,165.862	41,165.862
% of Prev. Year's Sales:	0%	0%	8%	43%	41%	1%	6%
Share of current Year's PQs:	-	109.053	5,940.961	33,015.648	31,522.508	449.548	4,771.210
Prev. Yr. Year-end Inv.:	17.376	48.558	2,210.758	6,269.182	5,076.349	887.877	1,988.425
Proj. Exports Current Year:	-		-	28.280	-		
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	(17.376)	115.021	6,700.683	43,282.570	42,207.413	(213.554)	5,168.390
calcualtion with 50% CRF	(17.376)	102.499	6,018.516	39,491.570	38,587.861	(265.174)	4,620.539
Further Calculation:							
Final MQ:	-	281.000	4,100.000	28,816.000	28,395.000	1,500.000	3,800.000
Total revised MQs:	66,892.000	+ others	14.025	=	66,906.025		

FURTHER CALCULATIONS

temp 11569 (b)(4) justified in an increase of 2230 kg but denied due to limitations of APQ - increase at least 2230

current PQ	76,134.014				Initial APQ	55,000.000
Current MQ	54,995.025				proposed APQ	59,000.000
inventory	17,099.249				Final Revised APQ	55,000.000
MQ need = PQx1.5-MQ-inventory	42,106.747		CFR 50%	33,364.709		
Lasy Year's APQ	55,000.000					
FDA est = APQ x est	58,740.000					
IMS est = APQ x est	58,080.000					

BASIC CLASS:	2011 Revised Quota Worksheets			9150					
PQ Total:	2,724.568 kg							FDA Est.:	12.80%
								IMS est:	11.0%
Company:	(b)(4)								
Request:	20.000	156.000	384.000	386.851	293.700	1,020.000	1,770.000	0.700	
Current Year MQ:	20.000	156.000	202.000	568	397.000	1,020.000	929.000	90.700	
Prev. Year's Sales:	-	-	117.530	399.348	278.332	1,066.927	802.610	3.087	
Total Prev. Year's Sales:	2,667.839	2,667.839	2,667.839	2,667.839	2,667.839	2,667.839	2,667.839	2,667.839	
% of Prev. Year's Sales:	0%	0%	4%	15%	10%	40%	30%	0%	
Share of current Year's PQs:	-	-	120.029	399.348	284.250	1,089.614	819.677	3.153	
Prev. Yr. Year-end Inv.:	-	-	23.376	47.697	84.963	420.709	644.651	21.254	
Proj. Exports Current Year:			-	120.58	-	22.250	-	-	
Revised MQs share PQ x 1.5 - YEI + exports									
Typcial calculation	-	-	156.668	671.905	341.413	1,235.962	584.864	(16.525)	
50% CFR inventory	-	-	156.043	671.905	339.933	1,230.290	580.597	(16.541)	
Final MQ:	20.000	156.000	176.000	672.000	397.000	1,020.000	929.000	90.700	
Total revised MQs:	3,460.700	+ others		0.025	=	3,460.725			

FURTHER CALCULATIONS

current PQ	*2,724.568*			Initial APQ	3,455.000
Current MQ	3,382.725			Proposed Final APQ	3,455.000
inventory	*1,242.688*			Final revised APQ	3,455.000
MQ need = PQx1.5-MQ-inventory	(538.561)	CFR 50%	(552.743)		
APQ last year	3,455.000				
FDA est = APQ x est	3,897.240				
IMS est = APQ x est	3,835.050				

BASIC CLASS:	2011 Revised Quota Worksh		9230				
PQ Total:	3,943.680 kg					FDA Est.:	-22.10%
						IMS:	-3.8%
Company:	(b)(4)						
Request:	0.005	3800	0.002	46.000	-	1,220.000	
Current Year MQ:	0.005	3800	0.005	46.000	2.000	1,287.483	
Prev. Year's Sales:	-	3374.714	-	-	-	1,006.754	
Total Prev. Year's Sales:	4,381.468	4,381.468	4,381.468	4,381.468	4,381.468	4,381.468	
% of Prev. Year's Sales:	0%	77%	0%	0%	0%	23%	
Share of current Year's PQs:	-	3,037.52	-	-	-	906.161	
Prev. Yr. Year-end Inv.:	-	896.124	0.001	-	-	502.422	
Proj. Exports Current Year:	-		-	20.000	-	69.600	
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	3,660.154	(0.001)	20.000	-	926.420	
calculation with CFR 50%	-	3,744.453	(0.001)	20.000	-	951.568	
Further Calculation:							
Final MQ:	0.005	3,800.000	0.002	46.000	-	1,220.000	
Total revised MQs:	5,066.007	+ others	-	=		5,066.007	

FURTHER CALCULATIONS

current PQ	3,943.680			Initial APQ	5,200.000
Current MQ	5,135.493			proposed APQ	5,200.000
inventory	1,398.547			Final Revised APQ	
MQ need = PQx1.5-MQ-inventory+export	(528.920)	CFR 50%	(509.073)		
last year APQ	6,600.000				
FDA est = APQ x est	5,141.400				
IMS est = APQ x est	6,349.200				

BASIC CLASS:	2011 Revised Quota Worksheet		9250 Methadone			
PQ Total:	16,149.065 kg				FDA Est.:	1.27%
					IMS:	-0.40%
Company:	(b)(4)					
Request:	4,884.000	316.000	11,000.000	3,960.000		
Current Year MQ:	4,948.000	316.000	11,000.000	2,530.000		
Prev. Year's Sales:	3,217.918	2.699	9,804.872	2,067.548		
Total Prev. Year's Sales:	15,093.040	15,093.040	15,093.040	15,093.040		
% of Prev. Year's Sales:	21%	0%	65%	14%		
Share of current Year's PQs:	3,443.068	2.868	10,490.896	2,212.210		
Prev. Yr. Year-end Inv.:	1,463.006	31.367	3,436.171	860.968		
Proj. Exports Current Year:	-	105.000	1,780.000	-		
Revised MQs share PQ x 1.3 - YEI + exports						
Typcial calculation	3,012.963	77.387	11,981.994	2,014.904		
calculation with CFR 50%	3,845.309	77.918	13,908.667	2,421.181		
Further Calculation:						
Final MQ:	4,948.000	316.000	11,811.000	2,530.000		
Total revised MQs:	19,605.000	+ others	0.004	=	19,605.004	

FURTHER CALCULATIONS

Update numbers below .

					Initial
				Initial APQ	20,000.000
current PQ	16,149.065			Proposed APQ	20,000.000
Current MQ	18,794.004			Final Revised APQ	20,000.000
Inventory	5,791.513				
MQ need = PQx1.3-MQ-inventory+export	(1,706.733)	CFR 50%	(625.926)		
APQ last year	20,000.000				
FDA est = APQ x est	20,254.000				
IMS est = APQ x est	19,920.000				

BASIC CLASS:	2011 Revised Quota Workshee		9300 Morphine				
PQ Total:	41,612.134 kg						FDA Est.: 6.60%
							IMS: 4.6%
Company:	(b)(4)						
Request:	32.000	227.5	2,218.000	17,000.000	13,432.000	362.000	
Current Year MQ:	32.000	102	1,125.000	17,000.000	13,432.000	1,750.000	
Prev. Year's Sales:	-	0	580.137	16,753.957	12,911.400	-	
Total Prev. Year's Sales:	30,247.116	30,247.116	30,247.116	30,247.116	30,247.116	30,247.116	
% of Prev. Year's Sales:	0%	0%	2%	55%	43%	0%	
Share of current Year's PQs:	0	-	798.117	23,049.070	17,762.715	-	
Prev. Yr. Year-end Inv.:	-	0	674.266	7,225.675	4,965.326	-	
Proj. Exports Current Year:	-		4.500	225.000	-	-	
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	-	527.410	27,572.930	21,678.747	-	
Calculation with CFR 50%	-	-	472.915	25,999.152	20,465.918	-	
Further Calculation:							
Final MQ:	32.000	10.000	975.000	20,083.000	15,907.000	1,750.000	
Total revised MQs:	38,757.000	+ others	0.105	=	38,757.105		

FURTHER CALCULATIONS

					Initial
current PQ	41,612.134			Initial APQ	39,000.000
Current MQ	33,941.105			Proposed APQ	39,000.000
inventory	12,875.818			Final Revised APQ	
MQ need = PQx1.5-MQ-inventory	15,601.278	CFR 50%	12,760.024		
last year APQ	39,000.000				
FDA est = APQ x est	41,574.000				
IMS est = APQ x est	40,794.000				

BASIC CLASS:	2011 Revised Quota Worksheets	Morphine	9300															
Company:	(b)(4)																	
Request:	194		334			2950			44000			16997			5110.6			
Current Year MQ:	194		10			2950			47000	Initial		17000			3200			
Year end Inventory	0		0			323			15262			5688			0			
Calculations	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild
codeine for sale	14.706	10.000	0.680		-					18,522.727	16,300.000	0.880	17,897.727	15,750.000	0.880	-	-	0.910
codeine for conversion							11,000.000	11,000.000	1.000	34,090.909	30,000.000	0.880	519.318	457.000	0.880	-	-	0.910
hdyromorphone	205.263	156.000	0.760		-		827.083	397.000	0.480	1,888.889	1,020.000	0.540						
dihydromorphine				389.888	347.000	0.890				2,210.526	2,100.000	0.950						
morphine (for sale)							1,308.140	1,125.000	0.860	1,339.286	1,125.000	0.840						
total need	219.97			389.888			13,135.223			58,052.337			18,417.045			-		
Revised MQ																		
total x 50% inventory - YEI	329.954			584.831			16,380.320			71,816.907			21,937.968			-		
previous MQ	244.000			-			9,100.000			50,000.000			12,500.000			4,511.000		
50% CRD calc.	141.961			477.360			15,421.515			22,803.823			3,458.707			(2,072.250)		
Final MQ	194.000			10.000			2,950.000			44,000.000			17,000.000			3,200.000		
Total revised MQs:	67344	+ others				=		67,344.000										

FURTHER CALCULATIONS

		Initial
Initial APQ	83,000.000	
Proposed Final APQ	83,000.000	
Final Revised APQ		

BASIC CLASS:	2010 Revised Quota Worksheets			9143 Oxycodone				FDA Est.:	12.60%
PQ Total:	95,268.818	kg						IMS:	4.9%
Company:	(b)(4)						total		
Request:	816.000	5,400.000	24,000.000	39,650.000	43,000.000	1.000	112,867.000		
Current Year MQ:	175.000	1,000.000	24,000.000	45,199.000	32,000.000	1.000	102,375.000		
Prev. Year's Sales:	28.753	449.023	21,434.699	27,415.752	24,802.197	226.567			
Total Prev. Year's Sales:	77,421.119	77,421.119	77,421.119	77,421.119	77,421.119	77,421.119			
% of Prev. Year's Sales:	0%	1%	28%	35%	32%	0%			
Share of current Year's PQs:	35.381	552.535	26,375.987	33,735.837	30,519.786	278.797			
Prev. Yr. Year-end Inv.:	1.793	557.332	13,264.017	10,896.620	10,710.482	482.250			
Proj. Exports Current Year:		-	6.700	1,100.000	10,000.000				
Revised MQs share PQ x 1.3 - YEI + exports									
Typcial calculation	44.203	160.964	21,033.466	34,059.969	38,965.240	(119.814)			
calculation with 50% CRF	49.622	245.593	25,073.342	39,227.115	43,639.800	(77.112)			
Further Calculation:									
Final MQ:	175.000	1,000.000	24,000.000	39,500.000	32,700.000	1.000			
Total revised MQs:	97,378.000		+ others	3.065	=	97,379.065			

FURTHER CALCULATIONS

						Initial
current PQ	95,268.818				Initial APQ	98,000.000
Current MQ	102,378.065				proposed revised	105,500.000
Inventory	36,676.793				Final Revised APQ	
MQ need = PQx1.3-MQ-Inventory	(15,205.395)		CFR 50%	(613.556)		
last year APQ	105,500.000					
FDA est = APQ x est	118,793.000					
IMS est = APQ x est	110,669.500					

BASIC CLASS: 2011 Revised Quota Work 9333 Thebaine

Company:	(b)(4)																					
Request:	2,563.000			1,500.000			3,500.000			40,000.000			24,000.000			11,000.000			27,000.000		
Current Year MQ:	662.000			-			1,735.000			50,000.000			17,000.000			9,933.000			27,000.000		
Year end inventory	272.289			-			46.850			4,602.336			3,914.700			3,597.650			11,929.000		
Calculations	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild
oxycodone				-	-	0.900	1,428.571	1,000.000	0.700	30,000.000	24,000.000	0.800	60,285.333	45,199.000	0.750		-		42,666.667	32,000.000	0.750
oxycodone for conversion										7,625.000	6,100.000	0.800									
hydrocodone	530.189	281.000	0.530														-		1,875.000	1,500.000	0.800
total need	530.189			-			1,428.571			37,625.000			60,285.333			12,400.000			44,541.667		
																supplies	(b)(4)				
Revised MQ																					
total x 50% inventory - YEI	523			0			2,096.007			51,835.164			88,483.300			15,092.350			54,883.500		
2010 MQ	416			0			30.000			43,000.000			23,500.000			8,049.000			29,500.000		
CFR 50% calc.	494.45			-			1,746.36			53,178.91			77,291.67			14,004.35			51,123.08		
Final MQ	662.000			0.000			1,746.000			51,000.000			67,793.000			6,000.000			39,723.083		
Total revised MQs:	166924	+ others	3.032			=		166,927.115											11,400.000	kg supplied by	(b)(4)

FURTHER CALCULATIONS

(b)(4) procures a 11400 kg from (b)(4)

(b)(4) supplies (b)(4) PQ = 5,600.000

Initial APQ	Initial	126,000	
Proposed Final APQ		126,000	
Final APQ		126,000	

rough calculation

oxycodone APQ	98000	0.690	142,028.986	thebaine needed
	proposed revised			

(b)(4)

September 14, 2011

Thomas H. Harrigan
Deputy Administrator - Designee
Office of the Administrator
Drug Enforcement Administration
Lincoln Place – West
700 Army Navy Dr
Arlington, VA 22202

RECEIVED
ODE
2011 SEP 21 AM 8:25

Reference: Request for the Immediate Increase in Quota for Oxymorphone (Drug Code 965

Dear Deputy Administrator Harrigan:

We are writing to request your assistance with an urgent matter that will impact our ability to rapidly convert to the new formulation of (b)(4) (oxymorphone HCl), (b)(4) (b)(4) This is a follow up to our June 1, 2011 letter to the Drug Enforcement Administration (DEA) and our July 13, 2011 meeting with DEA officials including Dr. Christine Sannerud and (b)(6) In order to ensure an uninterrupted supply of (b)(4) and to facilitate the conversion to the new formulation of (b)(4) (b)(4) is requesting that the DEA:

1) Raise the Revised Aggregate Production Quota for 2011 for oxymorphone (Drug Code 9652) to 3,670 kg, and
2) Make this quota grant effective as soon as possible.

The lack of additional quota for oxymorphone in 2011 will negatively impact our ability to move to the new formulation of (b)(4) quickly. (b)(4) is now faced with a situation where we may receive approval for the new formulation of (b)(4) on December 13, 2011 but will be unable to supply the new product until mid-2012. In addition, without the increase in 2011 quota, there is a possibility that the market may experience a drug shortage of the existing formulation of (b)(4) early in 2012.

The new formulation of (b)(4) provides an incremental benefit over the existing (b)(4) (b)(4) formulation and will provide some resistance to certain types of product manipulation. (b)(4) believes it is in the public's best interest for this formulation to be on the market as soon possible after the company receives approval from the FDA. (b)(4) is committed to exchanging the current formulation of (b)(4) with the new formulation of (b)(4)

(b)(4) It is critically important that the requested increase in oxymorphone quota be granted immediately in order to continue supplying patients with the existing formulation of (b)(4) while transitioning to the new formulation of (b)(4) as quickly as possible once it is approved,.

(b)(4) intends to minimize product inventories during the transition, but critical to this is allocating new oxymorphone quota to the formulation of (b)(4) (b)(4) We will minimize inventories by discontinuing the current formulation and manufacturing the new formulation of (b)(4) to keep inventory levels constant. (b)(4);(b)(7)(E)

Therefore, in order to facilitate a transition to the new formulation of (b)(4) (b)(4) as quickly as possible after approval, (b)(4) requests that DEA:

1) Raise the Revised Aggregate Production Quota for 2011 for oxymorphone (Drug Code 9652) to 3,670 kg, and
2) Make this quota grant effective as soon as possible.

We appreciate all of the efforts of the DEA in managing the aggregate production quotas and look forward to working with the Administration on our supply concerns. Please contact me if you have any questions or if you need any additional information.

Sincerely,

(b)(4);(b)(6)

cc: Wendy Goggin, Chief Counsel DEA
Joseph Rannazzisi, Deputy Chief of Operations for Diversion Control
Dr. Christine Sannerud, Chief UN Reporting and Quota Section

(b)(4)

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2011 OCT 18 AM 8:49

October 12, 2011

Dr. Christine Sannerud, Ph.D.
Chief, UN Reporting and Quota Section
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Reference: Docket No. DEA-343R – Comment to the 2011 Proposed Aggregate Production Quota for Oxymorphone (for sale) (Drug Code 9652)

Dear Dr. Sannerud:

This comment includes "CONFIDENTIAL BUSINESS INFORMATION" and the particular information in our comment that we request be redacted is prefaced by the word "CONFIDENTIAL" and is underlined and bracketed.

(b)(4) is a specialty pharmaceutical company based in (b)(4) engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used to treat and manage (b)(4) (b)(4) markets its branded pharmaceutical products to physicians in pain management, urology, endocrinology, oncology, neurology, surgery and primary care.

(b)(4) is pleased to offer comments to the Drug Enforcement Administration (DEA) for consideration as it proposes adjustments to the 2011 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

As provided in Docket No. DEA-343R[1], the DEA proposes "No Change" in the proposed adjusted 2011 quota for oxymorphone (for sale). In order to ensure an uninterrupted supply of (b)(4) (oxymorphone HCl), and to facilitate a rapid conversion to the new formulation of (b)(4) (b)(4) is requesting that the DEA:

[1] "Controlled Substances: 2011 Proposed Aggregate Production Quotas." Federal Register 76:178 (September 14, 2011) p. 56810.

(b)(4)

(b)(4)

1) Increase the revised aggregate production quota for 2011 for oxymorphone (for sale) (Drug Code 9652) to 3,670,000 grams, and

2) Make this quota grant to CONFIDENTIAL (b)(4) effective October 14, 2011 which is the conclusion of the formal comment period.

***

(b)(4) **requests that the DEA grant immediately an additional 600,000 grams of oxymorphone aggregate production quota.**

Over the past several months, (b)(4) has communicated with the DEA the need for an additional production quota grant of 600,000 grams of oxymorphone in 2011. This communication includes a letter to the DEA dated June 1, 2011, an in-person meeting with DEA officials (including Dr. Christine Sannerud and (b)(6) (b)(6) on July 13, 2011, and a second letter to the DEA dated September 14, 2011.

(b)(4)

A. Additional production quota is needed to build the necessary inventory to launch the new formulation of (b)(4)

The lack of additional quota for oxymorphone in 2011 will negatively impact (b)(4) ability to transition to the new formulation of (b)(4)

(b)(4)

(b)(4) believes that the new formulation of (b)(4) will provide an incremental benefit over the existing (b)(4) formulation and will provide some resistance to certain types of product manipulation and abuse. The company believes that it is in the public's best interest for this formulation to be on the market as soon as possible after the product is approved by the FDA.

(b)(4)

(b)(4)

B. (b)(4) is committed to ensuring that all 600,000 grams of additional quota is directed to manufacturing the new formulation of (b)(4)

(b)(4) is committed to allocating any additional quota granted by the DEA in 2011 exclusively to manufacturing the required launch volumes of the new formulation of (b)(4) None of the additional quota will be used to manufacture the existing formulation. If the Food and Drug Administration (FDA) ultimately were to not approve the New Drug Application (NDA) for the new formulation of (b)(4) then the additional 2011 quota would not be used. Therefore, the granting of additional quota will not result in an increase in inventory of the existing formulation of (b)(4)

C. CONFIDENTIAL [Allocating the remaining 2011 production quota and the entire 2012 quota to the new formulation of (b)(4) will result in a drug shortage of the existing formulation.]

CONFIDENTIAL [Redirecting all of the remaining 2011 supply and the entire 2012 supply of oxymorphone away from the current formulation of (b)(4) will result in a drug shortage. The result is that neither formulation of (b)(4) would be available to patients for a period of 3-6 months depending on strength. (b)(4) does not believe that this decision, which would create a drug shortage of (b)(4) would be in the best interests of the patients' who rely on this medication for management of their moderate to severe chronic pain. Such a shortage of (b)(4) would require patients to seek alternative therapies. Opioids differ in several ways including their potency, onset, and duration of action. The choice of opioid and the route of delivery is dependent on the specific patient's situation and medical needs. Conversion is not a simple process and can take weeks, and even several months, resulting in more clinical visits, an increase in monitoring for potential adverse events and the potential for loss of pain control.

Given the heightened patient concerns with prescription drug shortages, (b)(4) believes that taking steps that knowingly result in a drug shortage of (b)(4) may challenge public confidence in the supply and availability of prescription drugs.]

D. Validation batches of the new formulation of (b)(4) are insufficient to ensure a steady supply at launch.

The validation batches of the new formulation of (b)(4) will only supply a limited amount of product (1-4 weeks for most strengths) and are inadequate to launch the product. The validation batches will be the first units sold, but they would only be sufficient to meet a few weeks of sales. (b)(4) cannot responsibly go to market with the validation batches until we have ongoing resupply of the new formulation of (b)(4) coming from our manufacturer.

(b)(4)

(b)(4)

E. (b)(4) is committed to transitioning as quickly as possible to the new formulation of (b)(4) (b)(4)

(b)(4) intends to minimize product inventories during the transition, but critical to this is the allocation of additional oxymorphone quota to the formulation of (b)(4) (b)(4) will take a number of steps to quickly transition to the new formulation, including:

- (b)(4) intends to stop manufacturing and distributing the current formulation of (b)(4) as soon as sufficient inventory of the new formulation has been produced to enable launch.
- Upon launch of the new formulation, (b)(4) will destroy any of the current formulation of (b)(4) that is in our possession.
- (b)(4) intends to make every effort to remove the current formulation of (b)(4) from the distribution channel and exchange it with the new formulation of (b)(4) (b)(4) when the new formulation is launched. (b)(4) will destroy any of the current product that is returned.
- If granted the additional oxymorphone, (b)(4) will ensure that any of the API manufactured and processed with the additional oxymorphone quota will be quarantined at the API manufacturer until the new formulation of (b)(4) is approved by the FDA.

F. The DEA has previously exercised it authority to immediately grant additional production quota to manufacturers.

The DEA has previously exercised its authority to implement an expedited process to approve additional production quota when it recognized that without the immediate increase in quota, the supply of products to distributors and retail pharmacies would be impacted. To avoid such a situation, an interim notice was published making the revised aggregate production quotas effective immediately (Controlled Substances: 1999 Aggregate Production Quotas, 64 Fed. Reg. 46955 (August 27, 1999)). In the Register Notice, the DEA noted that due to the unforeseen and dramatic increase in sales of amphetamine, oxycodone and hydrocodone, the quotas for these three substances and four of the controlled substances used in their manufacture needed to be increased immediately. The Register Notice concluded that without the immediate increase, bulk manufacturers would not be able to produce the material needed by the dosage form manufacturers. This could, in turn, impact the supply of products to distributors and retail pharmacies.

(b)(4) believes that our existing quota circumstances are very similar to those previously acted upon by the DEA and the DEA should exercise its authority to immediately grant an additional 600,000 grams of production quota of oxymorphone.

(b)(4)

(b)(4) also believes that there is greater justification for the DEA to approve the immediate increase of 600,000 grams of oxymorphone (for sale) production quota since this material will be used to manufacture a new formulation of (b)(4) believes that is in the public's best interested for this formulation to be on the market as soon as possible after the product is approved by the FDA.

***

In order to ensure an uninterrupted supply of (b)(4) (oxymorphone HCl), and to facilitate the rapid conversion to the new formulation of (b)(4) (b)(4) is requesting that the DEA:

1) Increase the revised aggregate production quota for 2011 for oxymorphone (for sale) (Drug Code 9652) to 3,670,000 grams, and

2) Make this quota grant to CONFIDENTIAL (b)(4) effective October 14, 2011 which is conclusion of the formal comment period.

Please feel free to contact me if you have any questions or need additional information. Thank you very much for your consideration of this request.

Sincerely

(b)(4);(b)(6)

(b)(4)

(b)(4)

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

(b)(4)

RECEIVED
ODE
2011 OCT 12 AM 10: 5

October 5, 2011

Subject: Docket No. DEA-343R - Hydrocodone

Dear Federal Register Representative,

(b)(4) is a registered manufacturer (b)(4);(b)(7)(E) of Hydrocodone. We are providing comment to the proposed final aggregate production quota for 2011 for Hydrocodone based on the information provided below.

On February 23, 2011, (b)(4) requested an increase of 9,300 kg of 2011 Hydrocodone manufacturing quota over its then granted quota of 2,700 kg. We were granted an increase of 1,100 kg due to the limitations of the available aggregated production quota. As of September 30th (b)(4) has sold 8,075.735 kg (4,926.198 kg as base) and has forecasted sales of 3,000 kg (1,830 kg as base) for the balance of 2011. (b)(4) will be requesting 5,500 kg of quota in order to meet the balance of the 2011 sales and to allow (b)(4) to have some carryover inventory to meet Q1 2012 sales. Currently, (b)(4) pipeline is completely empty except for 39.7 kg (24.2 kg as base) of finished goods.

(b)(4) provided a copy of an *Active Ingredient Supply Agreement* between (b)(4) and a customer with the February 23rd letter. It documents that (b)(4) is contractually obligated to supply a minimum percentage of their Hydrocodone requirement.

(b)(4) respectfully requests that the 2011 aggregate production quota for Hydrocodone be increased by at least 5,500,000 grams to allow for our request. If you have any questions or require additional information, please feel free to contact me directly.

Sincerely,

(b)(4)
(b)(6)

DEA Compliance Manager

(b)(4)

(b)(4)

October 14, 2011

Acting Deputy Administrator
Drug Enforcement Administration
Washington, D.C. 20537

Attn: DEA Federal Register Representative [Docket No. DEA-343R]

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2011, as published in Federal Register on September 14, 2011, FR Vol 76, No. 178, pages 56810-56814.

In light of the fact that (b)(4) has no knowledge of either the amounts of any available aggregate quotas or the planned allocation of any aggregate, (b)(4) requests that DEA make any adjustments to the aggregate quotas sufficient to satisfy our requests for increased manufacturing quotas, which are outlined below. Because this comment contains proprietary information on our manufacturing quota needs, we also request that DEA treat this entire document as confidential.

All requests below are stated in grams anhydrous base ("AA").

9170 Diphenoxylate

(b)(4) requests that the revised aggregate be sufficient to include our request for 840,000 grams AA of Diphenoxylate manufacturing quota for 2011.

9801 Fentanyl

(b)(4) requests that the revised aggregate be sufficient to include our request for 810,000 grams AA of Fentanyl manufacturing quota for 2011.

8333 ANPP (Fentanyl Intermediate)

(b)(4) requests that the revised aggregate be sufficient to include our request for 1,400,000 grams AA of ANPP (Fentanyl Intermediate) manufacturing quota for 2011.

9193 Hydrocodone

(b)(4) requests that the revised aggregate be sufficient to include our request for 23,000,000 grams AA of Hydrocodone manufacturing quota for 2011.

9230 Meperidine

(b)(4) requests that the revised aggregate be sufficient to include our request for 1,600,000 grams AA of Meperidine manufacturing quota for 2011.

9250 Methadone

(b)(4) requests that the revised aggregate be sufficient to include our request for 14,000,000 grams AA of Methadone manufacturing quota for 2011.

9254 Methadone Intermediate

(b)(4) requests that the revised aggregate be sufficient to include our request for 16,000,000 grams AA of Methadone Intermediate manufacturing quota for 2011.

1724 Methylphenidate

(b)(4) requests that the revised aggregate be sufficient to include our request for 7,500,000 grams AA of Methylphenidate manufacturing quota for 2011.

9300 Morphine (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include our request for 47,000,000 grams AA of Morphine (for Conversion) manufacturing quota for 2011.

9300 Morphine (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include our request for 20,000,000 grams AA of Morphine (for Sale) manufacturing quota for 2011.

9668 Noroxymorphone

(b)(4) requests that the revised aggregate be sufficient to include our request for 4,900,000 grams AA of Noroxymorphone manufacturing quota for 2011.

9562 Oxymorphone (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include our request for 6,600,000 grams AA of Oxymorphone (for Conversion) manufacturing quota for 2011.

9652 Oxymorphone (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include our request for 2,850,000 grams AA of Oxymorphone (For Sale) manufacturing quota for 2011.

9143 Oxycodone (For Sale)

(b)(4) requests that the revised aggregate be sufficient to include our request for 26,000,000 grams AA of Oxycodone (For Sale) manufacturing quota for 2011.

9333 Thebaine

(b)(4) requests that the revised aggregate be sufficient to include our request for 42,000,000 grams AA of Thebaine manufacturing quota for 2011.

All other quota requests remain unchanged from (b)(4) original request.

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(4),(b)(6)

(b)(4)

Additional Diphenoxylate Quota Request
Supplemental Information

Exhibit A

	10/14/11								
	KN/LN								
		9170 Diphenoxylate sales							
		St. Louis (b)(7)(E)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Percent
(1)	Inventory	Bulk Controlled Substances		12,111	23,570			20,000	
(2)		In-Process Material		91,814	278,102			123,010	
(3)		Schedule 5 Material		189,548	155,301			260,340	
(4)		Total Inventory		293,473	456,972			403,350	
(5)	Inventory	Change		(64,603)	163,499			(53,622)	
E	(b)(4);(b)(7)(E)	(b)(4)	1593	606,351	477,336	377,402	184,000	561,402	71.6%
E			1593	46,534	0	129,260	0	129,260	16.5%
E			1593	0	0	0	39,560	39,560	5.0%
		Others	1593	1,489	3,506	2,622	0	2,622	0.3%
		TOTAL 1593 (C-V)		654,373	480,843	509,284	223,560	732,844	
		All Customers (C-II)	1592	93	93	0	0	0	0.0%
	Disposition	Domestic		654,466	480,936	509,284	223,560	732,844	
		All Export 1593 (C-V)		0	0	9,660	0	9,660	
		All Export 1592 (C-II)		9,083	8,673	41,552	0	41,552	
		Export		9,083	8,673	51,212	0	51,212	6.5%
(6)		Total Disposition		663,550	489,609	560,497	223,560	784,057	
(7)		Net Production		610,060	665,065			730,435	
(8)	15%	Non-recoverable waste		147,001	50,864			109,565	
(9)	Acquisition	Total Diphenoxylate Quota		757,061	715,929			840,000	
(10)		Quota previously granted		(760,000)	(820,000)			(480,000)	
(11)		**Diphenoxylate Quota needed**						**360,000**	
	Year Estimate = 365 Days in Year / 273 Days YTD * Actual YTD Domestic sales * Waste Factor							50% Rule	
	365/273 * 509284 * 1.15 = 783048			Production for Export * 1.15 = 58894				303,445	
	Producton for Inventory Build = (50% rule - Previous End) * Waste Factor = -176556								
	Total Production Calculated from History = 665,386 [Match with equation (09)]								

Contains Confidential and Proprietary Information

(b)(4)

Additional Fentanyl Quota Request
Supplemental Information

Exhibit B

	10/13/11								
	KN/LN								
		9801 Fentanyl Sales							
		(b)(7)(E)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer		2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Percent
(01)	Inventory	Bulk Controlled Substances		196,123	166,131			176,838	
(02)		In-Process Material		66,786	191,261			170,000	
(03)		Finished Dosage Forms		307	337			200	
(04)		Total Inventory		263,216	357,729			347,038	
(05)	Inventory	Change		107,762	94,513			(10,691)	
	(b)(4);(b)(7)(E)		5527	317,305	228,400	323,360	50,000	373,360	45.5%
			0129	140,844	145,164	156,410	21,290	177,700	21.7%
				0	47,471	71,587	25,953	97,540	11.9%
	(b)(4);(b)(7)(E)		0129	0	0	29,450	12,000	41,450	5.1%
			0129	13,226	30,085	10,170	5,420	15,590	1.9%
			1205	19,290	4,575	5,440	0	5,440	0.7%
			1130	0	3,051	2,512	721	3,233	0.4%
		Other HCl		2,730	7,455	5,600	2,560	8,160	1.0%
	Disposition	Domestic		493,395	466,201	604,529	117,944	722,473	
	Export	Fentanyl Alkaloid	0129	117,126	87,746	48,930	18,780	67,710	
		Fentanyl Citrate	1130	8,675	6,991	33,114	(2,605)	30,509	
		Export		125,800	94,737	82,044	16,175	98,219	12.0%
(06)		Total Fentanyl Sales		619,195	560,938	686,573	134,119	820,692	
(07)	Acquisitons	Net Fentanyl Production		742,887	561,060			810,000	
(08)		Quota previously granted		(775,000)	(620,000)			(670,000)	
(09)		**Fentanyl quota needed**						**140,000**	
	365 Days in Year / 273 Days YTD * Actual YTD Domestic sales = Year Estimate							50% Rule	
	365/273 * 604529 = 808253 + 50% rule - Previous End + Exports = 796,802							346,278	
		8333 Fentanyl Intermediate (ANPP)							
(11)	Inventory	Bulk Controlled Substances		183,488	95,631			457,169	
(12)		In-Process Material		0	0			0	
(13)		Total Inventory		183,488	95,631			457,169	
(14)	Inventory	Change		(446,740)	(87,857)			361,538	
(10)	(07)/78% Disposition	ANPP to Fentanyl		1,010,800	744,949			1,038,462	
(13)	Acquisition	Net Production		564,060	561,461			1,400,000	
(14)		Quota previously granted		0	0			(1,100,000)	
(15)		**ANPP quota needed**						**300,000**	

Contains Confidential and Proprietary Information

(b)(4)

Additional Hydrocodone Quota Request
Supplemental Information

Exhibit C

	10/14/11								
	KN/LN	9193 Hydrocodone							
		(b)(4)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Aug	Sep-Dec	CY 2011	
Type	Reg	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Percent
(01)	Inventory	Bulk Controlled Substances		3,501,188	2,384,077			4,093,687	
(02)		In-Process Material		4,031,197	3,885,062			4,000,000	
(03)		Total Inventory		7,532,385	6,269,140			8,093,687	
(04)	Inventory	Change		(2,078,956)	(1,263,245)			1,824,547	
E	(b)(4),(b)(7)(E)		1582	17,745,409	12,508,209	10,415,006	5,304,560	15,719,566	74.2%
E			1582	7,601,210	3,172,000	614,880	2,013,000	2,627,880	12.4%
E			1582	0	0	559,980	0	559,980	2.6%
E			1582	664,900	158,600	305,000	305,000	610,000	2.9%
E			1582	378,200	481,900	613,050	122,000	735,050	3.5%
E			1582	91,500	128,100	54,900	73,200	128,100	0.6%
E			1582	0	0	119,865	0	119,865	0.6%
E			1582	0	0	117,998	30,500	148,498	0.7%
E			1582	386,496	0	0	0	0	0.0%
E			1582	366,000	97,600	0	0	0	0.0%
		Domestic Others	1582	729,630	1,329,534	178,547	43,920	222,467	1.1%
		All Pollstirex		101,934	22,948	291,135	6,811	297,946	1.4%
		Base	1509	0	0	0	0	0	0.0%
	Disposition	Domestic		28,065,278	17,898,891	13,270,361	7,898,991	21,169,352	
(05)		Export		12,874	6,710	6,100	0	6,100	0.0%
(06)		Total Sales		28,078,152	17,905,601	13,276,461	7,898,991	21,175,452	
(07)	Acquisition	Net Production		26,911,100	17,674,562			23,000,000	
(08)		Quota previously granted		(31,043,000)	(22,000,000)			(22,000,000)	
(09)		**Additional Hydrocodone (for Sale) quota requested**						1,000,000	
(10)	(07)/94%	Hydrocodone Intermediates		30,932,299	18,802,726			24,468,085	
(11)		Hydrocodone from Thebaine						500,000	
(12)		Hydocodone from Codeine						23,968,085	
(13)	(11)/74%	Thebaine to Hydrocodone						675,676	
(14)	(12)/92%	Codeine to Hydrocodone		32,074,182	20,240,554			26,052,266	

(b)(4)

Additional Meperidine Quota Request
Supplemental Information

Exhibit D

	10/14/11								
	KN/LN								
		9230 Meperidine Sales							
		(b)(7)(E)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Percent
(01)	Inventory	Bulk Controlled Substances		622,536	200,046			208,888	
(02)		In-Process Material		223,319	302,376			320,000	
(03)		Total Inventory		845,855	502,422			528,888	
(04)	Inventory	Change		(658,128)	(343,433)			26,466	
E	(b)(4);(b)(7)(E)		1585	254,910	253,031	116,580	72,819	189,399	13.9%
E			1585	639,450	647,280	515,562	432,390	947,952	69.5%
E			1585	87,000	0	0	0	0	0.0%
E			1585	108,750	0	0	0	0	0.0%
						0	0	0	
		All Others	1585	12,772	22,925	70,888	0	70,888	
	Disposition	Domestic		1,102,882	923,235	703,030	505,209	1,208,239	
		Export		79,170	83,520	87,000	69,600	156,600	11.5%
(05)		Total Meperidine Sales		1,182,052	1,006,755	790,030	574,809	1,364,839	
(06)		Net Production		523,924	666,913			1,391,304	
(07)	15%	Non-recoverable waste		55,575	63,629			208,696	
(08)	Acquisition	Total Meperidine Production		584,447	730,542			1,600,000	
(09)		Quota Granted previously		(1,600,000)	(950,000)			(1,220,000)	
(10)		**Meperidine quota needed**						**380,000**	
	Year Estimate = 365 Days in Year / 273 Days YTD * Actual YTD Domestic sales * Waste Factor							50% Rule	
	365/273 * 703030 * 1.15 = 1,080,940			Production for Export * Waste factor = 180,090				532,868	
	Producton for Inventory Build = (50% rule - Previous End) * Waste Factor = 35,013								
	Total Production Calculated from History = 1,296,044 [Match with equation (08)]								

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(b)(4)

Additional Methadone Quota Request
Supplemental Information

Exhibit E

	10/14/11								
	KN/LN	9250 Methadone Sales							
		(b)(4)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Percent
(4)	Inventory	Bulk Controlled Substances		1,471,084	1,854,159			2,975,780	
(5)		In-Process Material		3,482,496	1,582,012			2,000,000	
(6)		Finished Dosage Forms		37,736	0			70,000	
(7)		Total Inventory		4,991,316	3,436,171			5,045,780	
(8)	Inventoy	Change		2,197,280	(1,555,145)			1,609,609	
E	(b)(4);(b)(7)(E)		6887	10,306,191	8,913,653	7,445,740	1,759,041	9,204,781	80.3%
F			1510	598,659	404,541	319,243	106,800	426,043	3.7%
E			1510	400,500	534,000	1,240,660	578,500	1,819,160	15.9%
		Others	1510	17,867	15,041	9,354	0	9,354	0.1%
		Methadone Base	3278	0	0	0	0	0	0.0%
(1)	Disposition	Domestic		11,323,217	9,867,235	9,014,997	2,444,341	11,459,338	
(2)		Export		268,792	13,359	15,166	0	15,166	0.1%
(3)		Total Sales		11,592,008	9,880,594	9,030,163	2,444,341	11,474,503	
(8)		Net Production		13,789,288	8,283,404			13,084,112	
(9)	7%	Non-recoverable waste		704,416	1,309,302			915,888	
(10)	Acquisition	Total Quota Production		13,645,168	9,592,706			14,000,000	
(11)		Quota previously granted		(14,000,000)	(12,000,000)			(11,000,000)	
(12)		**Additional Methadone quota needed**						**3,000,000**	
	Year Estimate = 365 Days in Year / 273 Days YTD * Actual YTD Domestic sales * Waste Factor							50% Rule	
	365/273 * 9014997 * 1.07 = 12,896,729 Production for Export * Waste Factor = 16,227							5,331,643	
	Producton for Inventory Build = (50% rule - Previous End) * Waste Factor = 2,028,155								
	Total Production Calculated from History = 14,941,111 [Match with Acquisitions]								
		9254 Methadone Intermediate							
(12)	Inventory	Bulk Controlled Substances		429,347	287,071			443,751	
(13)		In-Process Material		1,269,598	160,000			1,060,000	
(14)		Total Inventory		1,698,945	447,071			1,503,751	
(15)	Inventoy	Change		(2,700,184)	(1,251,874)			1,056,680	
(11)	(6)/97% Disposition	Methadone Intermediate to Methadone		12,097,775	8,950,885			13,488,775	
(15)		Net Production		9,397,591	7,714,681			14,545,455	
(16)	10%	Non-recoverable waste		767,876	764,521			1,454,545	
(17)	Acquisition	Total Methadone Intermediate		10,157,249	8,479,202			16,000,000	
(16)		Quota previously granted		(16,000,000)	(12,800,000)			(12,700,000)	
(17)		**Additional Methadone Intermediate quota needed**						**3,300,000**	

Contains Confidential and Proprietary Information

(b)(4)

Additional Methylphenidate Quota Request
Supplemental Information

Exhibit F

	10/14/11								
	KN/LN	1724 Methylphenidate Sales							
		(b)(4)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Percent
(01)	Inventory	Bulk Controlled Substances		4,930,293	776,833			1,011,849	
(02)		In-Process Material		2,010,670	1,347,108			1,400,000	
(03)		Total Inventory		6,940,963	2,123,941			2,411,849	
(04)	Inventory	Change		(2,353,812)	(4,817,022)			287,908	
E	(b)(4);(b)(7)(E)		1571	2,354,925	2,384,235	2,549,970	1,199,730	3,749,700	52.0%
E			1571	367,140	65,685	0	0	0	0.0%
E			8335	1,472,910	1,556,430	1,568,871	522,000	2,090,871	29.0%
E			1571	118,410	217,500	276,660	0	276,660	3.8%
E			1571	0	217,500	0	0	0	0.0%
E			1571	49,764	106,880	0	0	0	0.0%
E			1571	0	0	143,550	139,200	282,750	3.9%
		All Others		54,241	10,289	3,671	0	3,671	0.1%
E	(b)(4);(b)(7)(E)		7654	215,480	497,900	297,840	331,380	629,220	8.7%
		Other Base customers	7654	20,297	1,200	10,005	0	10,005	0.1%
	Disposition	Domestic		4,653,167	5,057,619	4,850,567	2,192,310	7,042,877	97.7%
		Export HCl	1571	25,238	24,287	12,615	156,600	169,215	
		Export Base	7654	0	0	0	0	0	
		Export		25,238	24,287	12,615	156,600	169,215	2.3%
(05)		Total Sales		4,678,405	5,081,906	4,863,182	2,348,910	7,212,092	
(06)	Acquisition	Net Production		2,330,548	362,629			7,500,000	
(07)		Quota previously granted		(6,000,000)	(7,300,000)			(5,730,000)	
(08)		**Additional Methylphenidate quota requested**						1,770,000	
	365 Days in Year / 273 Days YTD * Actual YTD Domestic sales = Year Estimate							50% Rule	
	365/273 * 4850567 = 6485191 + 50% rule - Previous End + Exports = 7,591,349							3,073,500	

(b)(4)

Additional Morphine (Conv) Quota Request
Supplemental Information

Exhibit G

	10/14/11							
	ME/LN	9300 Morphine (for Conversion)						
		(b)(4)				Actual	Firm+Forecast	
		Grams Base Class (AA)				AA grams	AA grams	AA grams
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total
(73)	Inventory	Bulk Controlled Substances		9,879,179	11,492,469			14,319,608
(74)		In-Process Material		2,985,662	3,769,130			4,500,000
(75)		Total Inventory		12,864,841	15,261,599			18,819,608
(76)	Inventory	Change		(4,472,377)	2,396,758			3,558,009
(77)	Disposition	Morphine (for Conversion)		66,778,404	26,451,626			43,441,992
(78)		Net Productrion		19,276,421	31,218,017			47,000,000
(79)		Non-recoverable waste		0	0			0
(80)	Acquisition	Morphine (for Conversion)		19,276,421	31,218,017			47,000,000
(81)		Quota previously granted		(63,000,000)	(50,000,000)			(44,000,000)
(82)		**Morphine (for Conversion) quota needed**						**3,000,000**
(83)	/95%	Morphine to Dihydromorphine		2,376,441	1,592,998			2,210,527
(84)	/61%	Morphine to Hydromorphone		0	0			10,943
(84)	/86%	Morphine to Codeine (for Sale)		17,233,446	12,272,568			17,686,632
(85)	/86%	Morphine to Codeine (for Conv)		47,168,517	25,566,289			23,533,891
(86)		Total Converted						43,441,992
		9170 Concentrate of Poppy Straw (High Morphine)						
(87)		Morphine (for Sale) Quota		17,596,393	16,433,985			20,000,000
(88)		Total Morphine Production		36,872,814	47,652,002			67,000,000
(89)		Raw Material Needed		41,430,128	53,541,575			75,280,898
(90)		Morphine from Opium		(34,032,069)	(24,231,838)			(31,000,000)
(91)	Inventory	Raw Material Inventory		11,217,237	18,894,558			1,027,255
(92)	Inventory	Change		10,521,970	7,677,321			(17,867,303)
(93)	Disposition	CPS (High Morphine) Needed		7,398,059	29,309,737			44,280,698
(94)	Acquisition	CPS (High Morphine) Quota		16,613,952	33,636,730			26,413,595
(95)		Quota previously granted		(65,000,000)	(43,000,000)			(35,600,000)
(96)		CPS (High Morphine) quota needed						(9,186,405)

(b)(4)

Additional Morphine Quota Request
Supplemental Information

Exhibit H

	10/14/11								
	KN/LN	9300 Morphine Sales							
		(b)(4)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011 Est	Est.Total	Ratio
(67)	Inventory	Bulk Controlled Substances		5,625,859	4,228,963			2,938,177	
(68)		In-Process Material		2,077,581	2,996,712			3,000,000	
(69)		Total Inventory		7,703,440	7,225,675			5,938,177	
(70)	Inventory	Change		732,636	(477,765)			(1,287,498)	
	(b)(4);(b)(7)(E)		1521	5,631,514	6,121,658	5,656,632	3,363,093	9,019,725	42.4%
			1521	5,062,500	4,856,250	4,168,355	786,078	4,954,433	23.3%
			1521	798,750	881,250	795,000	281,250	1,076,250	5.1%
			1521	1,238,955	890,865	1,126,326	373,674	1,500,000	7.0%
			1521	464,625	488,625	381,000	138,000	519,000	2.4%
			1521	192,900	282,000	131,250	0	131,250	0.6%
				0	0	321,803	156,750	478,553	2.2%
			1521	200,000	239,750	148,500	78,750	227,250	1.1%
			1521	408,938	112,500	244,800	75,000	319,800	1.5%
			1521	410,900	806,250	921,000	0	921,000	4.3%
			1521	296,250	0	225,038	0	225,038	1.1%
			1521	255,000	532,500	204,000	0	204,000	1.0%
			1521	446,549	0	0	0	0	0.0%
		Others		1,051,500	1,043,001	650,207	354,771	1,004,978	4.7%
		Morphine Base		353	353	0	0	0	0.0%
(71)	Disposition	Domestic		16,458,733	16,255,001	14,973,909	5,607,366	20,581,275	
(72)		Export	1521	606,000	491,119	706,223	0	706,223	3.3%
(73)		Total Sales		17,064,733	16,746,120	15,680,132	5,607,366	21,287,498	
(70)	Acquisitions	Total Morphine (for Sale)		17,596,393	16,433,985			20,000,000	
(71)		Quota previously granted		(22,000,000)	(19,346,450)			(17,000,000)	
(72)		**Additional Morphine (for Sale) quota needed**						**3,000,000**	
	Year Estimate = 365 Days in Year / 273 Days YTD * Actual YTD Domestic sales							50% Rule	
	365/273 * 14,973,909 = 20,020,061 Production for Export = 706,223							9,209,069	
	Producton for Inventory Build = (50% rule - Previous End) = 1,983,394								
	Total Production Calculated from History = 22,709,678 [Match with Acquisitions]								

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(b)(4)

Additional Noroxymorphone(Conv) Quota Request
Supplemental Information

	10/14/11							
	KN/LN	Products Made from Naltrexone				Actual	Firm+Forecast	
						AA grams	AA grams	AA grams
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011
		Customer	Code	2009 Act	2010 Act	2011 Act	2011Est	Est.Total
		(b)(4)	1251	1,054	209	0	0	0
			1251	3,400	14,112	4,704	0	4,704
			1479	195,000	340,000	154,215	175,085	329,300
			1479	236,000	100,000	58,000	14,000	72,000
			1479	25,000	0	75,000	0	75,000
			1479	123,983	194,000	43,100	52,000	95,100
			1479	346,500	472,500	300,000	175,000	475,000
			1479	74,000	239,000	71,000	0	71,000
			3940	120,612	58,680	0	73,350	73,350
		Others	3940	2,274	3,876	4,564	0	4,564
		Export	3940	0	0	2,119	0	2,119
		Domestic	5690	36	36	0	0	0
		Export	5690	2,200	0	0	0	0
(09)	Disposition	Domestic		1,130,059	1,422,414	712,702	489,435	1,202,137
(10)	Inventory	Bulk Naltrexone Base Equiv		965,772	468,705			432,447
(11)		In-Process as Naltrexone Base		745,200	48,785			311,000
		Total Inventory		1,710,972	517,490			743,447
(12)	Acquisitons	Naltrexone Net Production		480,227	228,931			1,428,094
(13)	/ 85%	Noroxymorphone to Naltrexone		564,973	295,029			1,680,111
		Products Made from Naloxone				Actual	Firm+Forecast	
						AA grams	AA grams	AA grams
				AA grams	AA grams	Jan-Jul	Aug-Dec	CY 2011
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011Est	Est.Total
		Domestic	1492	34,358	14,519	23,319	46,144	69,463
		Export	1492	324,000	658,896	588,583	310,236	898,819
(14)	Disposition	Naloxone Total		358,358	673,415	611,902	356,380	968,282
(15)	Inventory	Bulk Naloxone Base		9,900	196,659	297,464		295,200
(16)		In-Process Material		344,700	325,800	44,496		226,800
		Total Inventory		354,600	522,459	341,960		522,000
(17)	Acquisitons	Naloxone Net Production		154,958	841,274			967,823
(18)	/ 78%	Noroxymorphone to Naloxone		198,663	1,113,186			1,240,799

Contains Confidential and Proprietary Information

(b)(4)

Additional Noroxymorphone(Conv) Quota Request
Supplemental Information

		Products made from Nalbuphine				Actual	Firm+Forecast	
						AA grams	AA grams	AA grams
				AA grams	AA grams	Jan-Jul	Aug-Dec	CY 2011
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011Est	Est.Total
		(b)(4)	3310	159,250	151,060	144,326	13,650	157,976
		Others	3310	91	2,002	928	0	928
		Export	3310	121,578	238,420	180,599	138,093	318,691
(19)	Disposition	Nalbuphine Total		280,919	391,482	325,853	151,743	477,595
(20)	Inventory	Bulk Naltbuphine		154,700	14,560	144,690		172,900
(21)		In-Process Material		13,650	0	0		0
(22)	Acquisitons	Nalbuphine Net Production (from		226,319	237,692			635,935
		9668 Noroxymorphone						
(23)	Inventory	Bulk Noroxymorphone		465,277	430,787			168,856
(24)		In-Process Material		843,434	77,671			300,000
(25)		Total Inventory		1,308,711	508,458			468,856
(26)	Inventory	Change		(887,671)	(800,253)			468,856
(27)	/ 70%	Noroxymorphone to Nalbuphine		31,800	590,910			908,479
(28)	(12)	to Naltrexone		255,000	295,029			1,680,111
(29)	(17)	to Naloxone		586,000	1,113,186			1,240,799
(30)	Dispositions	Total Noroxymorphone (for Conv		872,800	2,360,000			3,829,389
(31)		Net Production		0	1,051,289			4,298,245
(32)	* 14%	Non-recoverable waste		0	147,180			601,754
(33)	Acquisitons	Total Noroxymorphone (for Conv		0	1,731,048			4,900,000
(34)		Quota previously granted		(2,000,000)	(8,300,000)			(3,200,000)
(35)		**Noroxymorphone (for Conversion) Quota needed**						1,700,000
		9652 Oxymorphone (for Conversion)						
(36)	Inventory	Bulk Oxymorphone (for Convers		862,613	632,651			739,735
(37)		In-Process Material		0	332,000			0
(38)		Total Inventory		862,613	964,651			739,735
(39)	Inventory	Change		862,613	102,038			(224,917)
(40)	(7) Dispositions	Oxymorphone to Noroxymorphone (for Sale)		3,192	3,192			2,305
(41)	(28)/63%	to Noroxymorphone (for Convers		0	3,276,219			6,822,612
(39)	Acquisitons	Net Production		862,613	3,399,617			6,600,000
(40)		Quota Granted		(3,900,000)	(9,900,000)			(4,700,000)
(41)		**Oxymorphone (for Conversion) Quota needed**						1,900,000

(b)(4)

Additional Oxycodone(for Sale)_Thebaine Quota Request
Supplemental Information

	10/14/11								
	KN/LN	9143 Oxycodone Sales							
		(b)(7)(E)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011Est	Est.Total	Percent
(21)	Inventory	Bulk Controlled Substances		5,361,985	2,235,623			6,451,484	
(22)		In-Process Material		6,607,916	11,026,394			6,600,000	
(23)		Finished Dosage Forms		221	0			5,000	
(24)		Total Inventory		11,970,122	13,264,017			13,056,484	
(25)	Inventory	Change		3,735,787	1,293,895			(207,533)	
E	(b)(4);(b)(7)(E)		8865	20,033,881	18,720,499	15,892,671	3,307,329	19,200,000	73.3%
E			8873	2,616,300	2,572,695	2,510,872	697,680	3,208,552	12.2%
E			8873	190,990	237,211	0	0	0	0.0%
E			8873	531,981	1,421,523	1,880,321	1,866,500	3,746,821	14.3%
		Others	8873	458,376	194,381	21,637	21,803	43,439	0.2%
		Oxy Terephthalate	6464	3	0	0	0	0	0.0%
	Disposition	Domestic		23,831,531	23,146,308	20,305,500	5,893,311	26,198,812	
		All Export	8865	1,744	4,114	42,977	(34,256)	8,721	0.0%
(26)		Total Oxycodone Sales		23,833,275	23,150,422	20,348,477	5,859,055	26,207,533	
(27)	Acquisition	Net Production		27,911,112	24,392,280			26,000,000	
(28)		Quota previously granted		(29,011,000)	(26,000,000)			(24,000,000)	
(29)		**Oxycodone (for Sale) quota needed**						**2,000,000**	
	Year Estimate = 365 Days in Year / 273 Days YTD * Actual YTD Domestic sales							50% Rule	
	365/273 * 20,305,500 = 27,148,379			Export = 8,721				12,336,280	
	Producton for Inventory Build = (50% rule - Previous End) = -927,737								
	Total Production Calculated from History = 26,229,363 [Match with Acquisitions]								

(b)(4)

Additional Oxycodone(for Sale)_Thebaine Quota Request
Supplemental Information

		9333 Thebaine						
(30)	Inventory	Bulk Controlled Substances	7,768,306	3,560,629			2,873,221	
(31)		In-Process Material	1,272,238	1,041,707			2,000,000	
(32)		Total Inventory	9,040,544	4,602,336			4,873,221	
(33)	Inventory	Change	2,578,511	(4,438,208)			270,885	
(34)		Oxycodone (for Conversion)	4,394,714	4,430,843			4,921,875	
(35)	(18) + (21)	Total Oxycodone production	32,305,826	28,823,123			30,921,875	
(36)		Oxycodone (Low ABKS)					5,494,720	
(37)	Disposition	Total Thebaine Dispositions	39,037,551	36,350,553			39,729,115	
(38)		Net Production	42,622,031	31,673,408			40,000,000	
(39)	5%	Non-recoverable waste	1,526,645	1,031,821			2,000,000	
(40)	Acquisition	Total Thebaine Quota	44,148,676	32,705,229			42,000,000	
(41)		Quota previously granted	(50,305,000)	(43,000,000)			(40,000,000)	
(42)		**Thebaine quota needed**					**2,000,000**	
(43)	/82% Conversion	Thebaine to Oxycodone (for Conv)					6,002,287	
(44)	/69%	Thebaine for Oxycodone Low ABKS					7,963,362	
(45)	/82%	Thebaine for Oxycodone 8865	39,037,551	36,062,247			25,006,439	
(46)	/80%	Thebaine to Oxycodone (for Sale)					32,969,801	
(47)	/74%	Thebaine for Hydrocodone		0			675,676	
(48)	/33%	Thebaine for Buprenorphine		288,306			81,352	
(49)	Conversion Total						39,729,115	

(b)(4)

Additional Oxymorphone (for Sale) Quota Request
Supplemental Information

Exhibit K

	10/14/11								
	KN/LN	9652 Oxymorphone Sales							
		(b)(4)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
				AA grams	AA grams	Jan-Sep	Oct-Dec	CY 2011	
Type	Registration	Customer	Code	2009 Act	2010 Act	2011 Act	2011Est	Est.Total	
(7)	Inventory	Bulk Controlled Substances		381,882	490,388			185,341	
(8)		In-Process Material		259,565	154,476			118,000	
(9)		Total Inventory		641,447	644,864			303,341	
(10)	Inventory	Change		425,223	3,417			(341,523)	
E	(b)(4);(b)(7)(E)		0790	1,059,410	1,676,920	1,895,329	434,543	2,329,871	73%
E			0790	92,719	162,229	0	206,925	206,925	6%
E			0790	0	144,848	0	496,620	496,620	16%
E			0790	0	0	63,311	0	63,311	2%
		Others	0790	14,899	144,839	61,688	33,108	94,796	3%
		Base Others	3433	0	0	0	0	0	0%
	Disposition	Domestic		1,167,027	2,128,836	2,020,328	1,171,196	3,191,523	
		Export	0881	24,831	0	0	0	0	0%
(11)		Total Sales		1,191,858	2,128,836	2,020,328	1,171,196	3,191,523	
(10)	Acquisition	Total Production		1,703,550	2,127,749			2,850,000	
(11)		Quota previously granted		(1,828)	(2,165,000)			(2,200,000)	
(12)		**Oxymorphone (for Sale) quota needed**						**650,000**	
	365 Days in Year /273 Days YTD * Actual YTD Domestic sales = Year Estimate							50% Rule	
	365/273 * 2020328 = 2701171 + 50% rule - Previous End + Exports = 3,727,920							1,330,090	
		9143 Oxycodone (for Conversion)							
(13)	Inventory	Bulk Controlled Substances		468,734	622,107			863,752	
(14)		In-Process Material		389,384	722,895			950,000	
(15)		Total Inventory		858,118	1,345,002			1,813,752	
(16)	Inventory	Change		3,828	486,884			468,750	
(17)	(05)/64% Disposition	Oxymorphone Oxymorphone (for Sale)		3,976,339	3,857,423			4,453,125	
(18)	Acquisition	Net Production		4,394,714	4,430,843			4,921,875	
(19)		Quota previously granted		(4,500,000)	(5,590,000)			(5,000,000)	
(20)		**Oxycodone (for Conversion) quota needed**						0	

Contains Confidential and Proprietary Information

SENT VIA E-MAIL

October 12, 2011

DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-343R

Dear Sirs:

I, (b)(4);(b)(7)(E) manufacturing registration (b)(7)(E) am submitting this comment on the 2011 Proposed Aggregate Production Quota for various products as published in the September 14, 2011 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) Alfentanil by 4,840 grams as base; (ii) Amphetamine (for sale) by 700,000 grams as base; (iii) Morphine (for Sale) by 1,125,000 grams as base; and (iv) Sufentanil by 200 grams as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

We feel the proposed quantities for the material mentioned above is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs. The appropriate DEA Form 189 will be submitted shortly pertaining to the items for which we submitted comments.

Very truly yours

(b)(4)

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September 26, 2011 **REVISION OCTOBER 12, 2011**

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No.DEA-343R (b)(4) **Comment**

Dear Sirs:

(b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) have previously submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2011 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Date of Correspondence	Action Needed
Manufacturing	109184 (b)(4) 109532 (b)(4)	Hydrocodone for Sale – 9193	July 25, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	**109722**	**Oxycodone for Sale – 9143**	**October 12, 2011**	**An aggregate increase based on (b)(4) customer demand**
Manufacturing	109524	Oxymorphone for Sale – 9652	September 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109138	Amphetamine – 1100	August 3, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	92075	Methylphenidate – 1724	August 15, 2011	An aggregate increase based on (b)(4) customer demand

Thank you in advance for considering these requests. If you have any questions regarding this request, please do not hesitate to contact me at (b)(4);(b)(6)

(b)(4);(b)(6)

Director, Process Engineering and DEA Compliance

(b)(4)

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September 26, 2011

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No.DEA-343R - (b)(4) Comment

Dear Sirs:

(b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) have previously submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2011 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Date of Correspondence	Action Needed
Manufacturing	109184 (b)(4) 109532 (b)(4)	Hydrocodone for Sale – 9193	July 25, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109131	Oxycodone for Sale – 9143	July 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109524	Oxymorphone for Sale – 9652	September 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109138	Amphetamine – 1100	August 3, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	92075	Methylphenidate – 1724	August 15, 2011	An aggregate increase based on (b)(4) customer demand

Thank you in advance for considering these requests. If you have any questions regarding this request, please do not hesitate to contact me at (b)(4);(b)(6)

Best regards

(b)(4);(b)(6)

Director, Process Engineering and DEA Compliance

(b)(4)

September 26, 2011

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No.DEA-343R - (b)(4) Comment

Dear Sirs:

(b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) have previously submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2011 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Date of Correspondence	Action Needed
Manufacturing	109184 (b)(4) 109532 (b)(4)	Hydrocodone for Sale – 9193	July 25, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109131	Oxycodone for Sale – 9143	July 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109524	Oxymorphone for Sale – 9652	September 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109138	Amphetamine – 1100	August 3, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	92075	Methylphenidate – 1724	August 15, 2011	An aggregate increase based on (b)(4) customer demand

Thank you in advance for considering these requests. If you have any questions regarding this request, please do not hesitate to contact me at (b)(4);(b)(6)

Best regards,

(b)(4);(b)(6)

Director, Process Engineering and DEA Compliance

2011 Final Revised Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The regulations require that DEA revise the aggregate production quota (APQ) annually after review of pertinent information provided from various sources including DEA-registered manufacturers and the Food and Drug Administration (FDA).

- The attached Federal Register seeks to establish the final revised APQ for 2011. A table summarizing the APQ and the changes made to the initial established value are attached for reference.

- OD is recommending an increase in the APQ for **alfentanil**. This increase is based on increased exportation requirements.

- OD is recommending an increase in the APQ for **diphenoxylate.** While the revised value is higher than the proposed revised 2011 APQ, it is still lower than the initial established 2011 APQ for diphenoxylate.

- OD is recommending an increase in the APQ for **gamma-hydroxybutyric acid (GHB).** (b)(4) is validating two new suppliers of gamma-butyrolactone, a list I chemical used to manufacture GHB.

- OD is recommending an increase in the APQ for **meperidine**. The increase is due to increased sales and while the revised value is higher than the proposed revised 2011 APQ, it is still lower than the initial established 2011 APQ for meperidine.

- OD is recommending an increase in the APQ for **pentobarbital.** The increase is due to increased sales and because (b)(4) now properly assesses their quota at the initial manufacturing stage vs. the final finished product. The majority of this increase is accounting for their manufacturing losses.

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-343F]

Controlled Substances:
Final Revised Aggregate Production Quotas for 2011

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice with request for comments. **SUMMARY:** This notice establishes final 2011 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA). DEA has taken into consideration comments received in response to a notice of the proposed revised aggregate production quotas for 2011 published September 14, 2011 (75 FR 56810).

DATES: Electronic comments must be submitted and written comments must be postmarked on or before [INSERT 30 DAYS FROM DATE OF PUBLICATION]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-343F" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov website for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish

to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, UN Reporting and Quota Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-7184.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot

be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. On September 15, 2010, a notice of proposed 2011 aggregate production quotas for certain controlled substances in Schedules I and II was published in the Federal Register (75 FR 56137). That notice stipulated that the Administrator would adjust, as needed, the quotas in 2011 as provided for in 21 CFR 1303.13. The 2011 established aggregate production quotas were subsequently published in the Federal Register (75 FR 79404) on December 20, 2010.

Additionally, on March 1, 2011, the DEA Administrator published a Final Order which temporarily placed five synthetic cannabinoids in Schedule I: 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200); 1-Butyl-3-(1-naphthoyl)indole (JWH-073); 1-Pentyl-3-(1-naphthoyl)indole (JWH-018); 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol; and 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (76 FR 11075). That Final Order stated that quotas for the five substances would be "established based on registrations granted and quota applications received pursuant to part 1303 of Title 21 of the Code of Federal

Regulations." 76 FR 11075. Aggregate productions quotas for these temporarily scheduled substances have not previously been established.

Analysis for Final Revised 2011 Aggregate Production Quotas

On September 14, 2011, a notice of the proposed revised 2011 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (75 FR 56810). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before October 14, 2011.

Six companies, 4 DEA registered manufacturers and two non-registrants, commented on a total of 22 schedule I and II controlled substances within the published comment period. Comments received proposed that the aggregate production quotas for 4-anilino-N-phenethyl-4-piperidine (ANPP), alfentanil, amphetamine (for sale), diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydrocodone, meperidine, methadone, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), pentobarbital, secobarbital, sufentanil, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has taken into consideration the above comments along with the relevant 2010 year-end inventories, initial 2011 manufacturing quotas, 2011 export requirements, actual and projected 2011 sales, research, product development requirements and additional applications received. Based on this information, the DEA has adjusted the final 2011 aggregate production quotas for alfentanil, diphenoxylate, gamma hydroxybutyric acid, hydrocodone, meperidine, methadone, noroxymorphone (for sale), oxycodone (for sale), oxymorphone (for sale), and

pentobarbital.

Regarding 4-anilino-N-phenethyl-4-piperidine (ANPP), fentanyl, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oxymorphone (for conversion), sufentanil, and thebaine, DEA has determined that the proposed revised 2011 aggregate production quotas are sufficient to meet the current 2011 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

The Administrator, therefore, orders that the 2011 final aggregate production quotas Schedule I and II controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Final Revised 2011 Quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g

Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	5,772,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g

Pholcodine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Final Revised 2011 Quotas
1-Phenylcyclohexylamine	2 g
1-Piperdinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g
Alfentanil	12,800 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	8,500,000 g
Amphetamine (for sale)	25,300,000 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	255,000 g
Diphenoxylate	730,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	59,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	2 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	2 g
Levorphanol	3,600 g
Lisdexamfetamine	10,400,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g

Methamphetamine	3,130,000 g
Methylphenidate	56,000,000 g
Morphine (for conversion)	70,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	10,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	401,000 g
Opium (powder)	63,000 g
Opium (tincture)	1,000,000 g
Oripavine	8,000,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	105,500,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	3,370,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	5,000 g
Tapentadol	403,000 g
Thebaine	116,000,000 g

Aggregate production quotas for all other Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated:

Michele M. Leonhart
Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODW: _____
ODQ:_____
ODQ:(b)(6)
Webcims #
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)