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Robert Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-363]

Controlled Substances: Final Adjusted Aggregate Production Quotas for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2012 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION:

Background

Section 306(a) 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. In accordance with 21 U.S.C. 826 and 21 CFR 1303.11, DEA published in the **Federal Register** on December 15, 2011, notice of the

established 2012 aggregate production quotas for controlled substances in Schedules I and II (76 FR 78044). That notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2012 as provided for in 21 CFR 1303.13. The 2012 proposed adjusted aggregate production quotas were subsequently published in the **Federal Register** on July 5, 2012 (77 FR 39737) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas on or before August 6, 2012.

Analysis for Final Adjusted 2012 Aggregate Production Quotas

Consideration has been given to the criteria outlined in the July 5, 2012, notice of proposed adjusted aggregate production quotas in accordance with 21 CFR 1303.13. In addition, nine companies, eight DEA registered manufacturers and one non-registrant, submitted timely comments regarding a total of 25 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 3,4-Methylenedioxy-N-Methylcathinone (methylone), alfentanil, amphetamine (for conversion), amphetamine (for sale), codeine (for conversion), codeine (for sale), desomorphine, dihydromorphine, hydrocodone (for sale), hydromorphone, levomethorphan, lisdexamfetamine, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), sufentanil, and tapentadol 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 2011 year-end inventories, initial 2012 manufacturing quotas, 2012 export requirements, actual and projected 2012 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator has determined that the proposed adjusted 2012 aggregate production quotas for 3,4-Methylenedioxypropionylvalerone (MDPV), 3,4-Methylenedioxy-N-Methylcathinone (methylone), 4-Methyl-N-Methylcathinone (mephedrone), alfentanil, amphetamine (for conversion), desomorphine, diethyltryptamine, dihydromorphine, gamma hydroxybutyric acid, hydrocodone (for sale), hydromorphone, levomethorphan, methadone, methadone intermediate, methylphenidate, morphine (for sale), oxycodone (for conversion), oxycodone (for sale), and sufentanil required additional consideration and hereby further adjusts the 2012 aggregate production quotas for those substances. Regarding amphetamine (for sale), codeine (for conversion), codeine (for sale), morphine (for conversion), noroxymorphone (for conversion), noroxymorphone (for sale), oripavine, oxymorphone (for conversion), oxymorphone (for sale), and tapentadol, the Administrator hereby determines that the proposed adjusted 2012 aggregate production quotas for these substances as published on July 5, 2012, at 77 FR 39737 are sufficient to meet the current 2012 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories. Pursuant to the above, the Administrator hereby establishes the 2012 final aggregate production quotas for Schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

	Final adjusted 2012 quotas
Basic Class—Schedule I	
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	12 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	30 g

	Final adjusted 2012 quotas
3,4-Methylenedioxy-N-methylcathinone (methylone)	30 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxymethamphetamine (MDMA)	30 g
3,4-Methylenedioxypyrovalerone (MDPV)	20 g
3,4,5-Trimethoxyamphetamine	12 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methylaminorex	12 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 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	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 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	12 g
Codeine-N-oxide	602 g
Desomorphine	10 g
Diethyltryptamine	18 g
Difenoxin	50 g
Dihydromorphine	3,750,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	37,000,000 g
Heroin	20 g
Hydromorphanol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	12 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N-Benzylpiperazine	12 g
N,N-Dimethylamphetamine	12 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphane	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

	Final adjusted 2012 quotas
Basic Class—Schedule II	
1-Phenylcyclohexylamine	2 g
1-Piperidinocyclohexanecarbonitrile	27 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g
Alfentanil	29,002 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	13,300,000 g
Amphetamine (for sale)	33,400,000 g
Carfentanil	5 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	400,000 g
Diphenoxylate	900,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	79,700,000 g
Hydromorphone	4,207,000 g
Isomethadone	4 g
Levo-alphaacetylmethadol (LAAM)	3 g
Levomethorphan	10 g
Levorphanol	3,600 g
Lisdexamfetamine	12,000,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	5 g
Meperidine Intermediate-B	9 g
Meperidine Intermediate-C	5 g
Metazocine	5 g
Methadone (for sale)	23,100,000 g
Methadone Intermediate	29,970,000 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	64,600,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	48,200,000 g
Nabilone	20,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	1,981,000 g
Opium (powder)	73,000 g
Opium (tincture)	1,000,000 g
Oripavine	15,300,000 g
Oxycodone (for conversion)	7,600,000 g
Oxycodone (for sale)	105,200,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	5,500,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	16,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	6,730 g
Tapentadol	5,400,000 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: August 31, 2012.

Michele M. Leonhart,
Administrator.

[FR Doc. 2012-22128 Filed 9-7-12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA 353]

Final Adjusted Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes the Final Adjusted 2012 Assessment of Annual Needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective Date:* September 10, 2012.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION: The 2012 Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and imported into the United States in 2012 to provide adequate supplies of each chemical for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks of such chemicals. Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires that the Attorney General establish an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100.

On July 18, 2012, a notice entitled "Proposed Adjustment of the Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and

Phenylpropanolamine for 2012" was published in the **Federal Register** (77 FR 42333). That notice proposed to adjust the 2012 Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the proposed assessments on or before August 17, 2012.

Comments Received

DEA did not receive any comments to the proposed adjustment of the assessment of annual needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale), and phenylpropanolamine (for conversion).

Conclusion

In determining the adjusted 2012 assessments, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407 respectively). DEA considered changes in demand, changes in the national rate of net disposal, and changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical; whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; whether any increased demand could be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the assessment of annual needs; whether any decreased demand would result in excessive inventory accumulation by all persons registered to handle the particular chemical; and other factors affecting the medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as found relevant.

Other factors that DEA considered include trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. The inventory, acquisition (purchases), and disposition (sales) data as provided by DEA-registered manufacturers and importers reflects the most current information available to DEA at the time of publication of this Notice. The underlying data used to determine the final 2012 assessment of annual needs is the same as that used in determining the proposed 2012 assessment of annual

needs, as published on September 14, 2011, at 76 FR 56809.

In accordance with 21 U.S.C. 826(a) and 21 CFR 1315.13, the Administrator hereby orders that the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, is adjusted and established as follows:

List I chemical	Final 2012 assessment of annual needs (kg)
Ephedrine (for sale)	4,300
Phenylpropanolamine (for sale)	5,800
Pseudoephedrine (for sale) ..	278,000
Phenylpropanolamine (for conversion)	26,200
Ephedrine (for conversion) ...	12,000

Dated: August 31, 2012.

Michele M. Leonhart,
Administrator.

[FR Doc. 2012-22127 Filed 9-7-12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Cambrex Charles City, Inc.

By Notice dated June 18, 2012, and published in the **Federal Register** on June 26, 2012, 77 FR 38085, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616-3466, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for internal use, and to manufacture bulk intermediates for sale to its customers. No comments or objections have been received. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Cambrex Charles City, Inc. to import the