

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration**

[Docket No. DEA-378]

**Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2014**

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

**ACTION:** Notice.

**SUMMARY:** This notice establishes the final adjusted 2014 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as the 2014 aggregate production quotas for three recently temporarily controlled substances.

**DATES:** Effective August 25, 2014.

**FOR FURTHER INFORMATION CONTACT:** Imelda Paredes, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:****Background**

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA) through 28 CFR 0.100(b). The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

The DEA published the 2014 established aggregate production quotas for controlled substances in schedules I and II and for the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the **Federal Register** (78 FR 55099) on September 9, 2013. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2014 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2014 proposed adjusted aggregate

production quotas for controlled substances in schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the **Federal Register** on June 12, 2014 (79 FR 33780) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 14, 2014.

**Analysis for Final Adjusted 2014 Aggregate Production Quotas and Assessment of Annual Needs**

Consideration has been given to the criteria outlined in the June 12, 2014, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding a total of 11 schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols 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. The DEA did not receive any comments for the proposed adjustments to the 2014 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

The DEA has taken into consideration the above comments along with the relevant 2013 year-end inventories, initial 2014 manufacturing and import quotas, 2014 export requirements, actual and projected 2014 sales, research and product development requirements, and the additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for opium tincture, oripavine, and ephedrine (for sale) required additional consideration and hereby further adjusts the 2014 aggregate production quota and assessment of annual needs for these substances. Regarding 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate,

hydromorphone, levorphanol, morphine (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols the Deputy Administrator hereby determines that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 12, 2014 (79 FR 33780) are sufficient to meet the current 2014 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2014 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed revised schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting revised established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Deputy Administrator hereby finalizes the 2014 aggregate production quotas for the following schedule I and II controlled substances and the 2014 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Final adjusted 2014 quotas (g)
<b>Schedule I</b>	
(1-Pentyl-1 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) .....	15
[1-(5-Fluoropentyl)-1 <i>H</i> -indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11) .....	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone) .....	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone) .....	15
1-(1-Phenylcyclohexyl)pyrrolidine .....	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201) .....	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694) .....	45
1-[1-(2-Thienyl)cyclohexyl]piperidine .....	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200) .....	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073) .....	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8) .....	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019) .....	45
1-Methyl-4-phenyl-4-propionoxypiperidine .....	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678) .....	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203) .....	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250) .....	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398) .....	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122) .....	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4) .....	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081) .....	45
2-(2,5-Dimethoxy-4- <i>n</i> -propylphenyl)ethanamine (2C-P) .....	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E) .....	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D) .....	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N) .....	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H) .....	30
2-(4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) .....	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C) .....	30
2-(4-Chloro-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) .....	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I) .....	30
2-(4-Iodo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5) .....	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone) .....	15
2,5-Dimethoxy-4-ethylamphetamine (DOET) .....	25
2,5-Dimethoxy-4- <i>n</i> -propylthiophenethylamine .....	25
2,5-Dimethoxyamphetamine .....	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2) .....	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4) .....	30
3,4,5-Trimethoxyamphetamine .....	25
3,4-Methylenedioxyamphetamine (MDA) .....	55
3,4-Methylenedioxymethamphetamine (MDMA) .....	50
3,4-Methylenedioxy- <i>N</i> -ethylamphetamine (MDEA) .....	40
3,4-Methylenedioxy- <i>N</i> -methylcathinone (methylone) .....	50
3,4-Methylenedioxypropylvalerone (MDPV) .....	35
3-Fluoro- <i>N</i> -methylcathinone (3-FMC) .....	15
3-Methylfentanyl .....	2
3-Methylthiofentanyl .....	2
4-Bromo-2,5-dimethoxyamphetamine (DOB) .....	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB) .....	25
4-Fluoro- <i>N</i> -methylcathinone (4-FMC) .....	15
4-Methoxyamphetamine .....	100
4-Methyl-2,5-dimethoxyamphetamine (DOM) .....	25
4-Methylaminorex .....	25
4-Methyl- <i>N</i> -ethylcathinone (4-MEC) .....	15
4-Methyl- <i>N</i> -methylcathinone (mephedrone) .....	45
4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP) .....	15
5-(1,1-Dimethylheptyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol .....	68
5-(1,1-Dimethyloctyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog) .....	53
5-Methoxy-3,4-methylenedioxyamphetamine .....	25
5-Methoxy- <i>N,N</i> -diisopropyltryptamine .....	25
5-Methoxy- <i>N,N</i> -dimethyltryptamine .....	25
Acetyl- <i>alpha</i> -methylfentanyl .....	2
Acetyldihydrocodeine .....	2
Acetylmethadol .....	2
Allylprodine .....	2
Alphacetylmethadol .....	2
<i>alpha</i> -Ethyltryptamine .....	25
Alphameprodine .....	2
Alphamethadol .....	2
<i>alpha</i> -Methylfentanyl .....	2

Basic class	Final adjusted 2014 quotas (g)
<i>alpha</i> -Methylthiofentanyl	2
<i>alpha</i> -Methyltryptamine (AMT)	25
<i>alpha</i> -Pyrrolidinobutiophenone ( $\alpha$ -PBP)	15
<i>alpha</i> -Pyrrolidinopentiophenone ( $\alpha$ -PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
<i>beta</i> -Hydroxy-3-methylfentanyl	2
<i>beta</i> -Hydroxyfentanyl	2
Betameprodine	2
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylamine	5
<i>gamma</i> -Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphanol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	650,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	2
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	175
<i>N</i> -(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
<i>N</i> -(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15
<i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	15
<i>N,N</i> -Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
<i>N</i> -Benzylpiperazine	25
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5
<i>N</i> -Ethylamphetamine	24
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24
Noracetylmethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
<i>para</i> -Fluorofentanyl	2
Parahexyl	5
Phenomorphane	2
Pholcodine	2
Properidine	2
Psilocybin	40
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	2

## Schedule II

1-Phenylcyclohexylamine	3
1-Piperidinocyclohexanecarbonitrile	3
4-Anilino- <i>N</i> -phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,625
Alphaprodine	3

Basic class	Final adjusted 2014 quotas (g)
Amobarbital .....	9
Amphetamine (for conversion) .....	18,375,000
Amphetamine (for sale) .....	49,000,000
Carfentanil .....	19
Cocaine .....	240,000
Codeine (for conversion) .....	68,750,000
Codeine (for sale) .....	46,125,000
Dextropropoxyphene .....	19
Dihydrocodeine .....	100,750
Diphenoxylate .....	1,288,750
Ecgonine .....	174,375
Ethylmorphine .....	3
Fentanyl .....	2,108,750
Glutethimide .....	3
Hydrocodone (for conversion) .....	137,500
Hydrocodone (for sale) .....	99,625,000
Hydromorphone .....	6,750,000
Isomethadone .....	5
Levo-alphaacetylmehtadol (LAAM) .....	4
Levomethorphan .....	195
Levorphanol .....	4,625
Lisdexamfetamine .....	23,750,000
Meperidine .....	6,250,000
Meperidine Intermediate-A .....	6
Meperidine Intermediate-B .....	11
Meperidine Intermediate-C .....	6
Metazocine .....	19
Methadone (for sale) .....	31,875,000
Methadone Intermediate .....	38,875,000
Methamphetamine .....	2,811,375

[1,250,000 grams of *l*-*deoxyephedrine* for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]

Methylphenidate .....	96,750,000
Morphine (for conversion) .....	91,250,000
Morphine (for sale) .....	62,500,000
Nabilone .....	30,375
Noroxymorphone (for conversion) .....	17,500,000
Noroxymorphone (for sale) .....	1,262,500
Opium (powder) .....	112,500
Opium (tincture) .....	780,000
Oripavine .....	30,625,000
Oxycodone (for conversion) .....	9,250,000
Oxycodone (for sale) .....	149,375,000
Oxymorphone (for conversion) .....	25,000,000
Oxymorphone (for sale) .....	7,750,000
Pentobarbital .....	35,000,000
Phenazocine .....	6
Phencyclidine .....	19
Phenmetrazine .....	3
Phenylacetone .....	45,750,000
Racemethorphan .....	3
Remifentanyl .....	5,875
Secobarbital .....	215,003
Sufentanyl .....	6,255
Tapentadol .....	17,500,000
Thebaine .....	145,000,000

#### List I Chemicals

Ephedrine (for conversion) .....	1,000,000
Ephedrine (for sale) .....	4,200,000
Phenylpropanolamine (for conversion) .....	44,800,000
Phenylpropanolamine (for sale) .....	5,300,000
Pseudoephedrine (for conversion) .....	5,000
Pseudoephedrine (for sale) .....	224,500,000

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 15, 2014.

**Thomas M. Harrigan,**  
*Deputy Administrator.*

[FR Doc. 2014–20137 Filed 8–22–14; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA–392]

#### Importer of Controlled Substances Application: CATALENT CTS, LLC; Correction

**ACTION:** Notice of correction.

In the Tuesday, June 17, 2014, **Federal Register** document number 2014–14123, Vol. 79, No. 116, page 34551, third column, the second paragraph, remove the first sentence from the paragraph: “In reference to drug code 7360, the company plans to import a synthetic cannabidiol.”

Dated: August 19, 2014.

**Joseph T. Rannazzisi,**  
*Deputy Assistant Administrator.*

[FR Doc. 2014–20119 Filed 8–22–14; 8:45 am]

BILLING CODE 4410–09–P

## MILLENNIUM CHALLENGE CORPORATION

[MCC FR 14–05]

#### Report on Countries That Are Candidates for Millennium Challenge Account Eligibility in Fiscal Year 2015 and Countries That Would Be Candidates But for Legal Prohibitions

**AGENCY:** Millennium Challenge Corporation.

**ACTION:** Notice.

**SUMMARY:** Section 608(d) of the Millennium Challenge Act of 2003 requires the Millennium Challenge Corporation to publish a report that identifies countries that are “candidate countries” for Millennium Challenge Account assistance during FY 2015. The report is set forth in full below.

Dated: August 19, 2014.

**Thomas G. Hohenthaner,**  
*Acting VP/General Counsel and Corporate Secretary, Millennium Challenge Corporation.*

#### Report on Countries That Are Candidates for Millennium Challenge Account Eligibility for Fiscal Year 2015 and Countries That Would Be Candidates but for Legal Prohibitions

##### Summary

This report to Congress is provided in accordance with section 608(a) of the Millennium Challenge Act of 2003, as amended, 22 U.S.C. 7701, 7707(a) (the Act).

The Act authorizes the provision of Millennium Challenge Account (MCA) assistance for countries that enter into a Millennium Challenge Compact with the United States to support policies and programs that advance the progress of such countries to achieve lasting economic growth and poverty reduction. The Act requires the Millennium Challenge Corporation (MCC) to take a number of steps in selecting countries with which MCC will seek to enter into a compact, including determining the countries that will be eligible for MCA assistance for fiscal year (FY) 2015 based on (a) a country’s demonstrated commitment to (i) just and democratic governance, (ii) economic freedom, and (iii) investments in its people; and (b) considering the opportunity to reduce poverty and generate economic growth in the country; and (c) the availability of funds to MCC. These steps include the submission of reports to the congressional committees specified in the Act and the publication of notices in the **Federal Register** that identify:

The countries that are “candidate countries” for MCA assistance for FY 2015 based on their per capita income levels and their eligibility to receive assistance under U.S. law and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act);

The criteria and methodology that the MCC Board of Directors (Board) will use to measure and evaluate the relative policy performance of the “candidate countries” consistent with the requirements of subsections (a) and (b) of section 607 of the Act in order to determine “eligible countries” from among the “candidate countries” (section 608(b) of the Act); and

The list of countries determined by the Board to be “eligible countries” for FY 2015, identification of such countries with which the Board will seek to enter into compacts, and a justification for such eligibility

determination and selection for compact negotiation (section 608(d) of the Act).

This report is the first of three required reports listed above.

##### Candidate Countries for FY 2015

The Act requires the identification of all countries that are candidates for MCA assistance for FY 2015 and the identification of all countries that would be candidate countries but for specified legal prohibitions on assistance. Under the terms of the Act, sections 606(a) and (b) set forth the two income tests countries must satisfy to be candidates for MCA assistance.<sup>1</sup> However for FY 2014, those categories are defined by MCC’s FY 2014 appropriations act, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2014, Public Law 113–76, Div. K (the FY 2014 SFOAA). Specifically, the FY 2014 SFOAA used the same definitions that have been used since the FY 2012 appropriations act and defines low income candidate countries as the 75 poorest countries as identified by the World Bank and provided that a country that changes during the fiscal year from low income to lower middle income (or vice versa) will retain its candidacy status in its former income category for the fiscal year and two subsequent fiscal years. Assuming these definitions will be used again in FY 2015, MCC is using them for purposes of this report.<sup>2</sup>

Under the redefined categories, a country will be a candidate for MCA assistance for FY 2015 if it:

Meets one of the following tests:  
Has a per capita income that is not greater than the World Bank’s lower middle income country threshold for such fiscal year (\$4,125 GNI per capita for FY 2015); and is among the 75

<sup>1</sup> Sections 606(a) and (b) of the Act provide that a country will be a candidate for MCA assistance if it (1) has a per capita income equal to or less than the historical ceiling of the International Development Association eligibility for the fiscal year involved (the “low income category”) or (2) is classified as a lower middle income country in the then most recent edition of the World Development Report for Reconstruction and Development published by the International Bank for Reconstruction and Development and has an income greater than the historical ceiling for International Development Association eligibility for the fiscal year involved (the “lower middle income category”); and is not ineligible to receive U.S. economic assistance under part I of the Foreign Assistance Act of 1961, as amended (the Foreign Assistance Act), by reason of the application of the Foreign Assistance Act or any other provision of law.

<sup>2</sup> If the language relating to the definition of low income candidate countries is not enacted or is changed for MCC’s FY 2015 appropriations act, MCC will revisit the selection process once the FY 2015 appropriations act is enacted and will conduct the selection process in accordance with the Act and applicable provisions for FY 2015.