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*Deputy Chief, Office of Offshore Regulatory Programs.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-418P]

#### **Proposed Adjustments to the 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 2015**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice with request for comments.

**SUMMARY:** The Drug Enforcement Administration proposes to adjust the 2015 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 7, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-418P" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully

submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

#### **SUPPLEMENTARY INFORMATION:**

##### **Posting of Public Comments**

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

The Freedom of Information Act (FOIA) applies to all comments received. 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 made publicly available 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 made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the 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. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

#### **Legal Authority and Background**

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA established the 2015 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014 (79 FR 53216). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

#### **Analysis for Proposed Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs**

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2015 to provide 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. The DEA is not proposing to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported into the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine,

and phenylpropanolamine by considering: (1) Changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting Administrator finds relevant.

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development,

and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As previously described in the published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers, 21 CFR 1303.24, 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. 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 adjusted schedule II controlled substance aggregate production quotas, and certain proposed adjusted schedule I controlled substance 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 adjusted established aggregate production quotas 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 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.

The Acting Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for certain schedule I and II controlled substances expressed in grams of anhydrous acid or base, as follows:

| Basic class   | Established 2015 Quotas | Proposed Adjusted 2015 Quotas |
|---|-------------------------|-------------------------------|
|   | (g)                     | (g)                           |
| <b>Schedule I</b>   |                         |                               |
| (1-Pentyl-1 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) .....                           | 15                      | 25                            |
| [1-(5-Fluoro-pentyl)-1 <i>H</i> -indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11) .....                 | 15                      | 25                            |
| [1-(5-fluoropentyl)-1 <i>H</i> -indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201) .....                            | 15                      | no change                     |
| 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone) .....  | 15                      | 25                            |
| 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone) .....  | 15                      | 25                            |
| 1-(1-Phenylcyclohexyl)pyrrolidine .....   | 10                      | no change                     |
| 1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201) .....   | 45                      | no change                     |
| 1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694) .....  | 45                      | no change                     |
| 1-[1-(2-Thienyl)cyclohexyl]piperidine .....   | 15                      | no change                     |
| 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200) .....  | 45                      | no change                     |
| 1-Butyl-3-(1-naphthoyl)indole (JWH-073) .....   | 45                      | no change                     |
| 1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8) .....   | 45                      | no change                     |
| 1-Hexyl-3-(1-naphthoyl)indole (JWH-019) .....   | 45                      | no change                     |
| 1-Methyl-4-phenyl-4-propionoxypiperidine .....  | 2                       | no change                     |
| 1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678) .....  | 45                      | no change                     |
| 1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203) .....   | 45                      | no change                     |
| 1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250) .....  | 45                      | no change                     |
| 1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398) .....   | 45                      | no change                     |
| 1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122) .....   | 45                      | no change                     |
| 1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4) .....   | 45                      | no change                     |
| 1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081) .....   | 45                      | no change                     |
| 2-(2,5-Dimethoxy-4- <i>n</i> -propylphenyl)ethanamine (2C-P) .....  | 30                      | no change                     |
| 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E) .....  | 30                      | no change                     |
| 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D) .....   | 30                      | no change                     |
| 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N) .....   | 30                      | no change                     |
| 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H) .....  | 30                      | no change                     |
| 2-(4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) ..... | 15                      | 25                            |
| 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C) .....   | 30                      | no change                     |

| Basic class   | Established<br>2015 Quotas | Proposed<br>Adjusted 2015<br>Quotas |
|---|----------------------------|-------------------------------------|
|   | (g)                        | (g)                                 |
| 2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimi-82).       | 15                         | 25                                  |
| 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)   | 30                         | no change                           |
| 2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimi-5).          | 15                         | no change                           |
| 2-(Methylamino)-1-phenylpentan-1-one (pentadron)  | 15                         | no change                           |
| 2,5-Dimethoxy-4-ethylamphetamine (DOET)   | 25                         | no change                           |
| 2,5-Dimethoxy-4-n-propylthiophenethylamine  | 25                         | no change                           |
| 2,5-Dimethoxyamphetamine  | 25                         | no change                           |
| 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)  | 30                         | no change                           |
| 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)  | 30                         | no change                           |
| 3,4,5-Trimethoxyamphetamine   | 25                         | no change                           |
| 3,4-Methylenedioxyamphetamine (MDA)   | 55                         | no change                           |
| 3,4-Methylenedioxymethamphetamine (MDMA)  | 50                         | no change                           |
| 3,4-Methylenedioxy-N-ethylamphetamine (MDEA)  | 40                         | no change                           |
| 3,4-Methylenedioxy-N-methylcathinone (methylo)  | 50                         | no change                           |
| 3,4-Methylenedioxypropylvalerone (MDPV)   | 35                         | no change                           |
| 3-Fluoro-N-methylcathinone (3-FMC)  | 15                         | 25                                  |
| 3-Methylfentanyl  | 2                          | no change                           |
| 3-Methylthiofentanyl  | 2                          | no change                           |
| 4-Bromo-2,5-dimethoxyamphetamine (DOB)  | 25                         | no change                           |
| 4-Bromo-2,5-dimethoxyphenethylamine (2-CB)  | 25                         | no change                           |
| 4-Fluoro-N-methylcathinone (4-FMC)  | 15                         | 25                                  |
| 4-Methoxyamphetamine  | 100                        | no change                           |
| 4-Methyl-2,5-dimethoxyamphetamine (DOM)   | 25                         | no change                           |
| 4-Methylaminorex  | 25                         | no change                           |
| 4-Methyl-N-ethylcathinone (4-MEC)   | 15                         | 25                                  |
| 4-Methyl-N-methylcathinone (mephedrone)   | 45                         | no change                           |
| 4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP)  | 15                         | 25                                  |
| 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol   | 68                         | no change                           |
| 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog). | 53                         | no change                           |
| 5-Methoxy-3,4-methylenedioxyamphetamine   | 25                         | no change                           |
| 5-Methoxy-N,N-diisopropyltryptamine   | 25                         | no change                           |
| 5-Methoxy-N,N-dimethyltryptamine  | 25                         | no change                           |
| Acetyl- $\alpha$ -methylfentanyl  | 2                          | no change                           |
| Acetyldihydrocodeine  | 2                          | no change                           |
| Acetylmethadol  | 2                          | no change                           |
| Allylprodine  | 2                          | no change                           |
| Alphacetylmethadol  | 2                          | no change                           |
| $\alpha$ -Ethyltryptamine   | 25                         | no change                           |
| Alphameprodine  | 2                          | no change                           |
| Alphamethadol   | 2                          | no change                           |
| $\alpha$ -Methylfentanyl  | 2                          | no change                           |
| $\alpha$ -Methylthiofentanyl  | 2                          | no change                           |
| $\alpha$ -Methyltryptamine (AMT)  | 25                         | no change                           |
| $\alpha$ -Pyrrolidinobutiophenone ( $\alpha$ -PBP)  | 15                         | 25                                  |
| $\alpha$ -Pyrrolidinopentiophenone ( $\alpha$ -PVP)   | 15                         | 25                                  |
| Aminorex  | 25                         | no change                           |
| Benzylmorphine  | 2                          | no change                           |
| Betacetylmethadol   | 2                          | no change                           |
| $\beta$ -Hydroxy-3-methylfentanyl   | 2                          | no change                           |
| $\beta$ -Hydroxyfentanyl  | 2                          | no change                           |
| Betameprodine   | 2                          | no change                           |
| Betamethadol  | 4                          | no change                           |
| Betaprodine   | 2                          | no change                           |
| Bufotenine  | 3                          | no change                           |
| Cathinone   | 70                         | no change                           |
| Codeine methylbromide   | 5                          | no change                           |
| Codeine-N-oxide   | 305                        | no change                           |
| Desomorphine  | 5                          | 25                                  |
| Diethyltryptamine   | 25                         | no change                           |
| Difenoxin   | 11,000                     | no change                           |
| Dihydromorphine   | 3,990,000                  | no change                           |
| Dimethyltryptamine  | 35                         | no change                           |
| Dipipanone  | 5                          | no change                           |
| Fenethylamine   | 5                          | no change                           |
| $\gamma$ -Hydroxybutyric acid   | 70,250,000                 | no change                           |
| Heroin  | 25                         | 50                                  |
| Hydromorphanol  | 2                          | no change                           |

| Basic class  | Established<br>2015 Quotas | Proposed<br>Adjusted 2015<br>Quotas |
|--|----------------------------|-------------------------------------|
|  | (g)                        | (g)                                 |
| Hydroxypethidine .....   | 2                          | no change                           |
| Ibogaine .....   | 5                          | no change                           |
| Lysergic acid diethylamide (LSD) .....   | 35                         | no change                           |
| Marihuana .....  | 658,000                    | no change                           |
| Mescaline .....  | 25                         | no change                           |
| Methaqualone .....   | 10                         | no change                           |
| Methcathinone .....  | 25                         | no change                           |
| Methyldesorphine .....   | 5                          | no change                           |
| Methyldihydromorphine .....  | 2                          | no change                           |
| Morphine methylbromide .....   | 5                          | no change                           |
| Morphine methylsulfonate .....   | 5                          | no change                           |
| Morphine- <i>N</i> -oxide .....  | 350                        | no change                           |
| <i>N</i> -(1-Adamantyl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (AKB48) .....  | 15                         | 25                                  |
| <i>N</i> -(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (ADB-PINACA) .....          | 15                         | 25                                  |
| <i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamide (AB-FUBINACA) .....   | 15                         | 25                                  |
| <i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide (AB-CHMINACA) ..... | 15                         | no change                           |
| <i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (AB-PINACA) .....               | 15                         | no change                           |
| <i>N,N</i> -Dimethylamphetamine .....  | 25                         | no change                           |
| Naphthylpyrovalerone (naphyrone) .....   | 15                         | 25                                  |
| <i>N</i> -Benzylpiperazine .....   | 25                         | no change                           |
| <i>N</i> -Ethyl-1-phenylcyclohexylamine .....  | 5                          | no change                           |
| <i>N</i> -Ethylamphetamine .....   | 24                         | no change                           |
| <i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine .....  | 24                         | no change                           |
| Noracymethadol .....   | 2                          | no change                           |
| Norlevorphanol .....   | 52                         | no change                           |
| Normethadone .....   | 2                          | no change                           |
| Normorphine .....  | 18                         | 40                                  |
| Para-fluorofentanyl .....  | zero                       | 5                                   |
| Parahexyl .....  | zero                       | 5                                   |
| Phenomorphan .....   | 2                          | no change                           |
| Pholcodine .....   | zero                       | 5                                   |
| Psilocybin .....   | 30                         | no change                           |
| Psilocyn .....   | 30                         | no change                           |
| Quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) .....                       | 15                         | 25                                  |
| Quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC) .....   | 15                         | 25                                  |
| Tetrahydrocannabinols .....  | 497,500                    | 511,250                             |
| Thiofentanyl .....   | 2                          | no change                           |
| Tilidine .....   | 10                         | 25                                  |
| Trimeperidine .....  | 2                          | no change                           |

## Schedule II

|  |            |            |
|--|------------|------------|
| 1-Phenylcyclohexylamine .....                            | 5          | no change  |
| 1-Piperidinocyclohexanecarbonitrile .....                | 5          | no change  |
| 4-Anilino- <i>N</i> -phenethyl-4-piperidine (ANPP) ..... | 2,687,500  | no change  |
| Alfentanil .....   | 17,750     | no change  |
| Alphaprodine .....                                       | 3          | no change  |
| Amobarbital .....  | 25,125     | no change  |
| Amphetamine (for conversion) .....                       | 21,875,000 | no change  |
| Amphetamine (for sale) .....                             | 37,500,000 | no change  |
| Carfentanil .....  | 19         | no change  |
| Cocaine .....  | 275,000    | no change  |
| Codeine (for conversion) .....                           | 50,000,000 | no change  |
| Codeine (for sale) .....                                 | 49,500,000 | 63,900,000 |
| Dextropropoxyphene .....                                 | 19         | 45         |
| Dihydrocodeine .....                                     | 226,375    | no change  |
| Diphenoxylate (for conversion) .....                     | 75,000     | no change  |
| Diphenoxylate (for sale) .....                           | 1,337,500  | no change  |
| Ecgonine .....   | 174,375    | no change  |
| Ethylmorphine .....                                      | 3          | no change  |
| Fentanyl .....   | 2,150,000  | 2,300,000  |
| Glutethimide .....                                       | 3          | no change  |
| Hydrocodone (for conversion) .....                       | 137,500    | no change  |
| Hydrocodone (for sale) .....                             | 99,625,000 | no change  |
| Hydromorphone .....                                      | 7,000,000  | no change  |
| Isomethadone .....                                       | 5          | no change  |
| Levo-alphaacetylmethadol (LAAM) .....                    | 4          | no change  |
| Levomethorphan .....                                     | 5          | 30         |
| Levorphanol .....  | 7,125      | no change  |

| Basic class                     | Established 2015 Quotas | Proposed Adjusted 2015 Quotas |
|---------------------------------|-------------------------|-------------------------------|
|                                 | (g)                     | (g)                           |
| Lisdexamfetamine .....          | 29,750,000              | no change                     |
| Meperidine .....                | 6,250,000               | no change                     |
| Meperidine Intermediate-A ..... | 6                       | no change                     |
| Meperidine Intermediate-B ..... | 11                      | 32                            |
| Meperidine Intermediate-C ..... | 6                       | no change                     |
| Metazocine .....                | 19                      | no change                     |
| Methadone (for sale) .....      | 31,875,000              | no change                     |
| Methadone Intermediate .....    | 34,375,000              | no change                     |
| Methamphetamine .....           | 2,061,375               | no change                     |

[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]

|                                       |             |             |
|---------------------------------------|-------------|-------------|
| Methylphenidate .....                 | 83,750,000  | 87,500,000  |
| Morphine (for conversion) .....       | 91,250,000  | no change   |
| Morphine (for sale) .....             | 62,500,000  | no change   |
| Nabilone .....                        | 18,750      | no change   |
| Noroxymorphone (for conversion) ..... | 17,500,000  | no change   |
| Noroxymorphone (for sale) .....       | 1,475,000   | no change   |
| Opium (powder) .....                  | 112,500     | no change   |
| Opium (tincture) .....                | 687,500     | no change   |
| Oripavine .....                       | 35,000,000  | no change   |
| Oxycodone (for conversion) .....      | 8,350,000   | no change   |
| Oxycodone (for sale) .....            | 137,500,000 | 139,150,000 |
| Oxymorphone (for conversion) .....    | 29,000,000  | no change   |
| Oxymorphone (for sale) .....          | 7,750,000   | no change   |
| Pentobarbital .....                   | 35,000,000  | no change   |
| Phenazocine .....                     | 6           | no change   |
| Phencyclidine .....                   | 19          | 38          |
| Phenmetrazine .....                   | 3           | no change   |
| Phenylacetone .....                   | 9,375,000   | no change   |
| Racemethorphan .....                  | 3           | no change   |
| Remifentanyl .....                    | 3,750       | 4,200       |
| Secobarbital .....                    | 215,003     | no change   |
| Sufentanyl .....                      | 6,255       | no change   |
| Tapentadol .....                      | 12,500,000  | no change   |
| Thebaine .....                        | 125,000,000 | no change   |

**List I Chemicals**

|  |             |           |
|--|-------------|-----------|
| Ephedrine (for conversion) .....           | 1,000,000   | no change |
| Ephedrine (for sale) .....                 | 4,000,000   | no change |
| Phenylpropanolamine (for conversion) ..... | 44,800,000  | no change |
| Phenylpropanolamine (for sale) .....       | 8,500,000   | no change |
| Pseudoephedrine (for conversion) .....     | 7,000       | no change |
| Pseudoephedrine (for sale) .....           | 224,500,000 | no change |

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may further adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

**Comments**

In accordance with 21 CFR 1303.13(c) and 1315.13(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments

received in response to this notice, the Acting Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.13(c) and 1315.13(e). In the event the Acting Administrator decides to hold such a hearing, the Acting Administrator will publish a notice of the hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the **Federal Register** a final order establishing any adjustment of the 2015 aggregate production quota for each basic class of controlled substance and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and

phenylpropanolamine. 21 CFR 1303.13(c) and 1315.13(f).

Dated: July 1, 2015.

**Chuck Rosenberg,**  
*Acting Administrator.*

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