## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–420N]**

### Proposed 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 2016

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

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

**SUMMARY:** The Drug Enforcement Administration proposes to establish the 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Interested persons may file written comments on or objections to this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 17, 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.

The Administrator may hold a public hearing on one or more issues raised by the comments received in response to this notice. In the event the Administrator decides in his 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 establishing the 2016 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**ADDRESSES:** To ensure proper handling of comments, please reference ''Docket No. DEA–420N'' 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 Morrissette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette 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. They will, unless reasonable cause is given, 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 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 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 confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much personal identifying information or confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as personal.

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

#### Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the 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 to establish the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

#### Analysis for Proposed 2016 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2016 aggregate production quotas and assessment of annual needs represent those quantities

of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2016 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 proposals include estimated imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include estimated imports of controlled substances for use in industrial processes.

In determining the proposed 2016 aggregate production quotas and assessment of annual needs, the Administrator has taken into account the criteria that is required to be considered in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The Administrator estimates the aggregate production quotas and assessment of annual needs for 2016 by considering the following factors: (1) Total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and chemical import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant.

Other factors the Administrator 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 2016 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessments of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The Administrator also 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 of concern 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 Administrator proposes to include in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (difenoxin, gamma-hydroxybutyric acid, and tetrahydrocannabinols), 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 proposed aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The Administrator 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 Administrator. The Administrator does not anticipate utilizing the reserve in the absence of these circumstances.

The Administrator, therefore, proposes to establish the 2016 aggregate production quotas for the following basic classes of schedule I and II controlled substances and 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 | Proposed 2016 quotas (g) |
|---|---|
| **Schedule I** | |
| (1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) | 25 |
| [1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11) | 25 |
| [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201) | 15 |
| 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone) | 25 |
| 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone) | 25 |
| 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-*n*-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 |

| Basic class | Proposed 2016 quotas (g) |
|---|---|
| 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) | 25 |
| 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C) | 30 |
| 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) | 25 |
| 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I) | 30 |
| 2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5) | 15 |
| 2-(Methylamino)-1-phenylpentan-1-one (pentedrone) | 25 |
| 2,5-Dimethoxy-4-ethylamphetamine (DOET) | 25 |
| 2,5-Dimethoxy-4-*n*-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-*N*-ethylamphetamine (MDEA) | 40 |
| 3,4-Methylenedioxy-*N*-methylcathinone (methylone) | 50 |
| 3,4-Methylenedioxypyrovalerone (MDPV) | 35 |
| 3-Fluoro-*N*-methylcathinone (3-FMC) | 25 |
| 3-Methylfentanyl | 2 |
| 3-Methylthiofentanyl | 2 |
| 4-Bromo-2,5-dimethoxyamphetamine (DOB) | 25 |
| 4-Bromo-2,5-dimethoxyphenethylamine (2-CB) | 25 |
| 4-Fluoro-*N*-methylcathinone (4-FMC) | 25 |
| 4-Methoxyamphetamine | 150 |
| 4-Methyl-2,5-dimethoxyamphetamine (DOM) | 25 |
| 4-Methylaminorex | 25 |
| 4-Methyl-*N*-ethylcathinone (4-MEC) | 25 |
| 4-Methyl-*N*-methylcathinone (mephedrone) | 45 |
| 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP) | 25 |
| 5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol | 68 |
| 5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog) | 53 |
| 5-Methoxy-3,4-methylenedioxyamphetamine | 25 |
| 5-Methoxy-*N,N*-diisopropyltryptamine | 25 |
| 5-Methoxy-*N,N*-dimethyltryptamine | 25 |
| Acetyl-*alpha*-methylfentanyl | 2 |
| Acetyldihydrocodeine | 2 |
| Acetylmethadol | 2 |
| Allylprodine | 2 |
| Alphacetylmethadol | 2 |
| *alpha*-Ethyltryptamine | 25 |
| Alphameprodine | 2 |
| Alphamethadol | 2 |
| *alpha*-Methylfentanyl | 2 |
| *alpha*-Methylthiofentanyl | 2 |
| *alpha*-Methyltryptamine (AMT) | 25 |
| *alpha*-Pyrrolidinobutiophenone (α-PBP) | 25 |
| *alpha*-Pyrrolidinopentiophenone (α-PVP) | 25 |
| Aminorex | 25 |
| Benzylmorphine | 2 |
| Betacetylmethadol | 2 |
| *beta*-Hydroxy-3-methylfentanyl | 2 |
| *beta*-Hydroxyfentanyl | 2 |
| Betameprodine | 2 |
| Betamethadol | 4 |
| Betaprodine | 2 |
| Bufotenine | 3 |
| Cathinone | 70 |
| Codeine methylbromide | 5 |
| Codeine-*N*-oxide | 305 |
| Desomorphine | 25 |
| Diethyltryptamine | 25 |
| Difenoxin | 11,000 |
| Dihydromorphine | 3,000,000 |
| Dimethyltryptamine | 35 |
| Dipipanone | 5 |
| Fenethylline | 5 |
| *gamma*-Hydroxybutyric acid | 70,250,000 |
| Heroin | 50 |
| Hydromorphinol | 2 |
| Hydroxypethidine | 2 |
| Ibogaine | 5 |
| Lysergic acid diethylamide (LSD) | 40 |

| Basic class | Proposed 2016 quotas (g) |
|---|---|
| Marihuana | 200,000 |
| Mescaline | 25 |
| Methaqualone | 10 |
| Methcathinone | 25 |
| Methyldesorphine | 5 |
| Methyldihydromorphine | 2 |
| Morphine methylbromide | 5 |
| Morphine methylsulfonate | 5 |
| Morphine-*N*-oxide | 350 |
| *N*-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48) | 25 |
| *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) | 25 |
| *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) | 25 |
| *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA) | 15 |
| *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA) | 15 |
| *N,N*-Dimethylamphetamine | 25 |
| Naphthylpyrovalerone (naphyrone) | 25 |
| *N*-Benzylpiperazine | 25 |
| *N*-Ethyl-1-phenylcyclohexylamine | 5 |
| *N*-Ethylamphetamine | 24 |
| *N*-Hydroxy-3,4-methylenedioxyamphetamine | 24 |
| Noracymethadol | 2 |
| Norlevorphanol | 52 |
| Normethadone | 2 |
| Normorphine | 40 |
| Para-fluorofentanyl | 5 |
| Parahexyl | 5 |
| Phenomorphan | 2 |
| Pholcodine | 5 |
| Psilocybin | 30 |
| Psilocyn | 50 |
| Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) | 25 |
| Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC) | 25 |
| Tetrahydrocannabinols | 511,250 |
| Thiofentanyl | 2 |
| Tilidine | 25 |
| Trimeperidine | 2 |
| **Schedule II** | |
| 1-Phenylcyclohexylamine | 5 |
| 1-Piperidinocyclohexanecarbonitrile | 5 |
| 4-Anilino-*N*-phenethyl-4-piperidine (ANPP) | 2,950,000 |
| Alfentanil | 17,750 |
| Alphaprodine | 3 |
| Amobarbital | 25,125 |
| Amphetamine (for conversion) | 15,000,000 |
| Amphetamine (for sale) | 37,500,000 |
| Carfentanil | 19 |
| Cocaine | 200,000 |
| Codeine (for conversion) | 50,000,000 |
| Codeine (for sale) | 63,900,000 |
| Dextropropoxyphene | 45 |
| Dihydrocodeine | 226,375 |
| Diphenoxylate (for conversion) | 31,250 |
| Diphenoxylate (for sale) | 1,337,500 |
| Ecgonine | 125,000 |
| Ethylmorphine | 3 |
| Fentanyl | 2,300,000 |
| Glutethimide | 3 |
| Hydrocodone (for conversion) | 235,000 |
| Hydrocodone (for sale) | 88,500,000 |
| Hydromorphone | 7,000,000 |
| Isomethadone | 5 |
| Levo-alphacetylmethadol (LAAM) | 4 |
| Levomethorphan | 30 |
| Levorphanol | 7,125 |
| Lisdexamfetamine | 29,750,000 |
| Meperidine | 5,450,000 |
| Meperidine Intermediate-A | 6 |
| Meperidine Intermediate-B | 11 |
| Meperidine Intermediate-C | 6 |
| Metazocine | 19 |

| Basic class | Proposed 2016 quotas (g) |
|---|---|
| Methadone (for sale) | 31,875,000 |
| Methadone Intermediate | 34,375,000 |
| Methamphetamine | 2,061,375 |
| [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 | 87,500,000 |
| Morphine (for conversion) | 91,250,000 |
| Morphine (for sale) | 62,500,000 |
| Nabilone | 18,750 |
| Noroxymorphone (for conversion) | 17,500,000 |
| Noroxymorphone (for sale) | 1,475,000 |
| Opium (powder) | 112,500 |
| Opium (tincture) | 687,500 |
| Oripavine | 30,000,000 |
| Oxycodone (for conversion) | 6,250,000 |
| Oxycodone (for sale) | 139,150,000 |
| Oxymorphone (for conversion) | 29,000,000 |
| Oxymorphone (for sale) | 7,750,000 |
| Pentobarbital | 38,125,000 |
| Phenazocine | 6 |
| Phencyclidine | 50 |
| Phenmetrazine | 3 |
| Phenylacetone | 50 |
| Racemethorphan | 3 |
| Remifentanil | 3,750 |
| Secobarbital | 215,003 |
| Sufentanil | 6,255 |
| Tapentadol | 25,500,000 |
| Thebaine | 125,000,000 |
| **List I Chemicals** | |
| Ephedrine (for conversion) | 100,000 |
| Ephedrine (for sale) | 4,000,000 |
| Phenylpropanolamine (for conversion) | 22,400,000 |
| Phenylpropanolamine (for sale) | 8,500,000 |
| Pseudoephedrine (for conversion) | 7,000 |
| Pseudoephedrine (for sale) | 224,500,000 |

The Administrator further proposes that the aggregate production quotas for all other basic classes of 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 Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as necessary.

Dated: July 13, 2015.

**Chuck Rosenberg,**

*Acting Administrator.*

[FR Doc. 2015–17561 Filed 7–16–15; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Registration: Meda Pharmaceuticals, Inc.

**ACTION:** Notice of registration.

**SUMMARY:** Meda Pharmaceuticals, Inc. applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Meda Pharmaceuticals, Inc. registration as an importer of this controlled substance.

**SUPPLEMENTARY INFORMATION:** By notice dated March 20, 2015, and published in the **Federal Register** on March 27, 2015, 80 FR 16426, Meda Pharmaceuticals, Inc., 705 Eldorado Street, Decatur, Illinois 62523 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Meda Pharmaceuticals, Inc. to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of nabilone (7379) a basic class of controlled substance listed in schedule II.