

## INTERNATIONAL TRADE COMMISSION

[USITC SE-14-023]

### Sunshine Act Meetings

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** July 11, 2014 at 11 a.m.

**PLACE:** Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205-2000.

**STATUS:** Open to the public.

#### MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701-TA-515-521 and 731-TA-1251-1257 (Preliminary)(Certain Steel Nails from India, Korea, Malaysia, Oman, Taiwan, Turkey, and Vietnam). The Commission is currently scheduled to complete and file its determinations on July 14, 2014; views of the Commission are currently scheduled to be completed and filed on July 21, 2014.

5. Outstanding action jackets: None. In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: June 30, 2014.

**William R. Bishop,**  
*Supervisory Hearings and Information Officer.*

[FR Doc. 2014-15679 Filed 6-30-14; 4:15 pm]

**BILLING CODE 7020-02-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-393]

#### 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 2015

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

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

**SUMMARY:** The Drug Enforcement Administration proposes to establish the 2015 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 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 1, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-393" on all electronic and written correspondence. The DEA 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. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Erika Gehrmann, 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 made publicly available, 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 publicly available. 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. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the **FOR FURTHER INFORMATION CONTACT** paragraph above.

#### Legal Authority

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 pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR part 0 subpart R, App.

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

The proposed year 2015 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 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 include

imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances necessary to provide for the medical, scientific, or other legitimate needs of the United States.

In determining the proposed 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into account the criteria that the DEA is required to consider 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 DEA proposes the aggregate production quotas and assessment of annual needs for 2015 by considering: (1) Total net disposal of the 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 such 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 in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. 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 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The DEA 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 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 proposes to include in all schedule II aggregate production quotas, and certain schedule

I aggregate production quotas (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 resulting 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 resulted 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 Deputy Administrator, therefore, proposes to establish the 2015 aggregate production quotas for the following 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 established 2015 quotas (g)
<b>Schedule I</b>	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoropentyl)-1H-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-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
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(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)-N-(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)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15

Basic class	Proposed established 2015 quotas (g)
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 (methylo) .....	50
3,4-Methylenedioxypropylvalerone (MDPV) .....	35
3-Fluoro-N-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-N-methylcathinone (4-FMC) .....	15
4-Methoxyamphetamine .....	100
4-Methyl-2,5-dimethoxyamphetamine (DOM) .....	25
4-Methylaminorex .....	25
4-Methyl-N-ethylcathinone (4-MEC) .....	15
4-Methyl-N-methylcathinone (mephedrone) .....	45
4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP) .....	15
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol .....	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-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 ( $\alpha$ -PBP) .....	15
alpha-Pyrrolidinopentiophenone ( $\alpha$ -PVP) .....	15
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 .....	200
Desomorphine .....	5
Diethyltryptamine .....	25
Difenoxin .....	50
Dihydromorphine .....	3,990,000
Dimethyltryptamine .....	35
Dipipanone .....	5
Fenethylamine .....	5
gamma-Hydroxybutyric acid .....	70,250,000
Heroin .....	25
Hydromorphanol .....	2
Hydroxypethidine .....	2
Ibogaine .....	5
Lysergic acid diethylamide (LSD) .....	35
Marihuana .....	21,000
Mescaline .....	25
Methaqualone .....	10
Methcathinone .....	25
Methyldesorphine .....	5
Methyldihydromorphine .....	2

Basic class	Proposed established 2015 quotas (g)
Morphine methylbromide .....	5
Morphine methylsulfonate .....	5
Morphine-N-oxide .....	350
N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48) .....	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA) .....	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) .....	15
N,N-Dimethylamphetamine .....	25
Naphthylpyrovalerone (naphyrone) .....	15
N-Benzylpiperazine .....	25
N-Ethyl-1-phenylcyclohexylamine .....	5
N-Ethylamphetamine .....	24
N-Hydroxy-3,4-methylenedioxyamphetamine .....	24
Noracymethadol .....	2
Norlevorphanol .....	52
Normethadone .....	2
Normorphine .....	18
Phenomorphan .....	2
Psilocybin .....	30
Psilocyn .....	30
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) .....	15
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC) .....	15
Tetrahydrocannabinols .....	497,500
Thiofentanyl .....	2
Tilidine .....	10
Trimeperidine .....	2

## Schedule II

1-Phenylcyclohexylamine .....	5
1-Piperidinocyclohexanecarbonitrile .....	5
4-Anilino-N-phenethyl-4-piperidine (ANPP) .....	2,687,500
Alfentanil .....	17,625
Alphaprodine .....	3
Amobarbital .....	25,125
Amphetamine (for conversion) .....	21,875,000
Amphetamine (for sale) .....	37,500,000
Carfentanil .....	19
Cocaine .....	240,000
Codeine (for conversion) .....	50,000,000
Codeine (for sale) .....	46,125,000
Dextropropoxyphene .....	19
Dihydrocodeine .....	101,375
Diphenoxylate .....	1,337,500
Ecgonine .....	174,375
Ethylmorphine .....	3
Fentanyl .....	2,108,750
Glutethimide .....	3
Hydrocodone (for conversion) .....	137,500
Hydrocodone (for sale) .....	99,625,000
Hydromorphone .....	6,250,000
Isomethadone .....	5
levo-Alphacetylmethadol (LAAM) .....	4
Levomethorphan .....	5
Levorphanol .....	3,375
Lisdexamfetamine .....	29,750,000
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 .....	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 .....	83,750,000
Morphine (for conversion) .....	91,250,000
Morphine (for sale) .....	62,500,000
Nabilone .....	18,750
Noroxymorphone (for conversion) .....	17,500,000

Basic class	Proposed established 2015 quotas (g)
Noroxymorphone (for sale) .....	1,475,000
Opium (powder) .....	112,500
Opium (tincture) .....	687,500
Oripavine .....	22,750,000
Oxycodone (for conversion) .....	8,350,000
Oxycodone (for sale) .....	137,500,000
Oxymorphone (for conversion) .....	21,875,000
Oxymorphone (for sale) .....	7,750,000
Pentobarbital .....	35,000,000
Phenazocine .....	6
Phencyclidine .....	19
Phenmetrazine .....	3
Phenylacetone .....	9,375,000
Racemethorphan .....	3
Remifentanyl .....	3,750
Secobarbital .....	215,003
Sufentanyl .....	6,255
Tapentadol .....	12,500,000
Thebaine .....	125,000,000
<b>List I Chemicals</b>	
Ephedrine (for conversion) .....	1,000,000
Ephedrine (for sale) .....	3,000,000
Phenylpropanolamine (for conversion) .....	44,800,000
Phenylpropanolamine (for sale) .....	8,500,000
Pseudoephedrine (for conversion) .....	7,000
Pseudoephedrine (for sale) .....	224,500,000

The Deputy 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. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as necessary.

#### Comments

In accordance with 21 CFR 1303.11(c) and 1315.11(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 Deputy Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.11(c) and 1515.11(e). In the event the Deputy Administrator decides to hold such a hearing, the Deputy 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 Deputy Administrator will issue and publish in the **Federal Register** a final order establishing the 2015 aggregate production quota for each basic class of controlled substance and establishing the assessment of annual needs for the list I chemicals ephedrine,

pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.11(c) and 1315.11(f).

Dated: June 26, 2014.

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

[FR Doc. 2014-15549 Filed 7-1-14; 8:45 am]

**BILLING CODE 4410-09-P**

#### OFFICE OF MANAGEMENT AND BUDGET

##### **Draft 2014 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities**

**AGENCY:** Executive Office of the President, Office of Management and Budget.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** The Office of Management and Budget (OMB) requests comments on its Draft 2014 Report to Congress on the Benefits and Costs of Federal Regulations, available at: [http://www.whitehouse.gov/omb/inforeg\\_regpol\\_reports\\_congress/](http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/). The Draft Report is divided into two parts. Part I contains two chapters. Chapter I examines the benefits and costs of major Federal regulations issued in fiscal year 2013 and summarizes the benefits and costs of major regulations issued

between October 2003 and September 2013. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II offers recommendations for regulatory reform. Part II summarizes agency compliance with the Unfunded Mandates Reform Act.

OMB requests that comments be submitted electronically to OMB by September 2, 2014 through [www.regulations.gov](http://www.regulations.gov).

**DATES:** To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by September 2, 2014.

**ADDRESSES:** Submit comments by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Direct comments to Docket ID OMB-2014-0002

- *Fax:* (202) 395-7285

- *Mail:* Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mabel Echols, NEOB, Room 10202, 725 17th Street NW., Washington, DC 20503. To ensure that your comments are received, we recommend that comments on this draft report be electronically submitted.

All comments and recommendations submitted in response to this notice will be made available to the public, including by posting them on OMB's Web site. For this reason, please do not