1308.24(a). All other requirements of the CSA and the CFR apply, including, but not limited to, registration as an importer as required by 21 U.S.C. 957.

Chemical Preparations Containing Newly Controlled Substances

The statutory authority for exempt chemical preparations is based on the control status of substances contained within a preparation, the intended administration of a preparation, and the packaged form of a preparation. DEA conducts a case-by-case analysis of each application for exemption to determine whether exemption of a preparation from certain provisions of the CSA is appropriate pursuant to the specified statutory and regulatory requirements.

Most exempt chemical preparations have remained effective until the holder of a specific exempt chemical preparation specifically requested that the exemption be terminated. The CSA allows for modifications to the controlled substances schedules to add, remove, or change the schedule of substances thus resulting in periodic modifications to the control status of various substances. 21 U.S.C. 811(a). Since the CSA was enacted in 1970, DEA has on several occasions added to, removed from, or modified the schedules of controlled substances in accordance with the CSA. Such changes may result in the non-compliance of exempt chemical preparations with current statutes or regulations if chemical preparations that have already obtained exempt status contain newly controlled substances. For example, although an exempt chemical preparation may continue to be packaged in the same manner as when it was approved, non-controlled substances in the preparation may become controlled, thus prompting the need for a new application for exemption of the chemical preparation to ensure continued compliance. Other preparations that previously contained no controlled substances may contain newly controlled substances and thus would require an application for exemption.

DEA reviews applications for chemical preparation exemptions based on the statutes and regulations that are in place at the time of the application, including the control status of substances included in the preparation. DEA must remain vigilant to ensure that exempt chemical preparations remain consistent with the standards set forth in the CSA and its implementing regulations. As such, DEA reminds the public that any chemical preparation, regardless of whether it was previously exempt, that contains a newly controlled substance will require a new application for exemption pursuant to 21 U.S.C. 811(g)(3)(B) and 21 CFR 1308.23–1308.24.

Review of Exemptions Pursuant to 21 U.S.C. 811(g)(3)

Based on inquiries received from industry, DEA is conducting a comprehensive review of the exempt chemical preparation regulations. DEA's regulations at 21 CFR 1308.24(a) state that approved chemical preparations are exempt from certain provisions of both Subchapter I and Subchapter II of the CSA: ''The chemical preparations and mixtures approved pursuant to 1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and 1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section.'' Pursuant to its regulations, DEA has provided exemptions from the application of section 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and 21 CFR 1301.74 since the implementation of the regulations in the early 1970s. Until DEA's analysis of the exemption regulations is complete, DEA will continue to review and provide exemptions to chemical preparations consistent with the implementing regulations, when warranted. DEA will publish a future notice regarding the outcome of DEA's review of its regulations with respect to the exemption of chemical preparations.

Opportunity for Comment

Pursuant to 21 CFR 1308.23, any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Deputy Assistant Administrator will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed.

Approved Exempt Chemical Preparations Are Posted on DEA's Web Site

A list of all current exemptions, including those listed in this order, is available on DEA's Web site at *http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf.* The dates of applications of all current exemptions are posted for easy reference.

Dated: June 17, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2013–16010 Filed 7–2–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–378]

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

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes initial year 2014 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before August 2, 2013. 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–378'' on all electronic and written correspondence. DEA encourages that all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at *http://www.regulations.gov* for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *www.regulations.gov* will be posted for public review and are part of the official docket record. Written comments submitted via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive,

Springfield, VA 22152, Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket 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 posted online or made available in the public docket, 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. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. The Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

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 for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The proposed year 2014 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 2014 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 for use in industrial processes.

In determining the proposed 2014 aggregate production quotas and assessment of annual needs, DEA has taken into account the criteria that 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). DEA proposes the aggregate production quotas and assessment of annual needs for 2014 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 pursuant to 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 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 2014 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

DEA 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, 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. 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 DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Deputy Administrator, therefore, proposes that the year 2014 aggregate production quotas and assessment of annual needs for the following Schedule I and II controlled substances and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—schedule I	Proposed 2014 quotas
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
1-(1-Phenylcyclohexyl)pyrrolidine	10 g
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g

Basic class—schedule I	Proposed 2014 quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	30 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30 g
2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N)	30 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	25 g
2,5-Dimethoxyamphetamine	25 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30 g
3,4,5-Trimethoxyamphetamine	25 g
3,4-Methylenedioxyamphetamine (MDA)	55 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	50 g
3,4-Methylenedioxypyrovalerone (MDPV)	35 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25 g
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25 g
4-Methoxyamphetamine	100 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	25 g
4-Methyl-N-methylcathinone (mephedrone)	45 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	25 g
5-Methoxy-N,N-diisopropyltryptamine	25 g
5-Methoxy-N,N-dimethyltryptamine	25 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	25 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	25 g
Aminorex	25 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	26 g
Codeine Methylbromide	5 g
Codeine-N-oxide	200 g
Desomorphine	5 g
Diethyltryptamine	25 g
Difenoxin	50 g
Dihydromorphine	3,300,000 g
Dimethyltryptamine	25 g
Dipipanone	5g
Fenethylline	5 g
Gamma-hydroxybutyric acid	70,250,000 g
Heroin	25 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	25 g
Methaqualone	10 g
Methcathinone	25 g
Methyldihydromorphine	2 g
Morphine Methylbromide	5 g
Morphine Methylsulfonate	5 g
Morphine-N-oxide	175 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
N-Benzylpiperazine	25 g
N,N-Dimethylamphetamine	25 g
N-Ethyl-1-phenylcyclohexylamine	5 g
N-Ethylamphetamine	24 g
N-Hydroxy-3,4-methylenedioxyamphetamine	24 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Parahexyl	5 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	30 g
Psilocyn	30 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic class—schedule II	Proposed 2014 quotas
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile (PCC)	3 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500 g
Alfentanil	17,625 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	18,375,000 g
Amphetamine (for sale)	49,000,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	68,750,000 g
Codeine (for sale)	46,125,000 g
Dextropropoxyphene	19 g
Dihydrocodeine	100,750 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	5,968,750 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	2,000 g
Lisdexamfetamine	23,750,000 g
Meperidine	6,250,000 g
Meperidine Intermediate-A	6 g

Basic class—schedule II	Proposed 2014 quotas
Meperidine Intermediate-B ...	11 g
Meperidine Intermediate-C ...	6 g
Metazocine	6 g
Methadone (for sale)	31,875,000 g
Methadone Intermediate	38,875,000 g
Methamphetamine	3,911,375 g
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,600,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)].	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	62,500,000 g
Nabilone	30,375 g
Noroxymorphone (for conversion)	12,250,000 g
Noroxymorphone (for sale) ...	1,262,500 g
Opium (powder)	112,500 g
Opium (tincture)	625,000 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	9,250,000 g
Oxycodone (for sale)	149,375,000 g
Oxymorphone (for conversion)	17,250,000 g
Oxymorphone (for sale)	7,750,000 g
Pentobarbital	35,000,000 g
Phenazocine	6 g
Phencyclidine	6 g
Phenmetrazine	3 g
Phenylacetone	29,980,050 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	17,500,000 g
Thebaine	145,000,000 g

Basic class—list I chemicals	Proposed 2014 quotas
Ephedrine (for conversion) ...	15,100,000 g
Ephedrine (for sale)	2,900,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	5,300,000 g
Pseudoephedrine (for conversion)	5,000 g
Pseudoephedrine (for sale) ..	156,000,000 g

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 be established 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 2014 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR 1315.11, 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. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy 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 Deputy Administrator will publish in the **Federal Register** a Final Order establishing the 2014 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated: June 27, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–16052 Filed 7–2–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

[OMB Number 1121–0219]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Juvenile Residential Facility Census (Extension, Without Change, of a Currently Approved Collection)

ACTION: 60 Day Notice.

The Department of Justice (DOJ), Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until September 3, 2013. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Brecht Donoghue, (202) 305–1270, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection Back to Top

(1) *Type of information collection:* Extension, without change, of a currently approved collection.

(2) *The title of the form/collection:* Juvenile Residential Facility Census.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CJ–15, Office of Juvenile Justice and Delinquency Prevention, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Federal Government, State, Local or Tribal. Other: Not-for-profit institutions; Business or other for-profit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 2,545 respondents will complete a 2-hour questionnaire.

(6) *An estimate of the total public burden (in hours) associated with the collection:* Approximately 5,090 hours.

If additional information is required, contact: Jerri Murray, Department Clearance Officer, U.S. Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3W–1407B, Washington, DC 20530.