Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-363]

Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2012 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION]*. 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-363" on all electronic and written correspondence. DEA encourages 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 the http://www.regulations.gov website 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. Should you, however, wish to submit written comments via regular or express mail, they 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, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the 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. Please note that 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 that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. 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 2012 established aggregate production quotas for controlled substances in schedules I and II were published in the Federal Register (76 FR 78044) on December 15, 2011. That notice stipulated that, as provided for in 21 CFR 1303.13, all aggregate production quotas are subject to adjustment.

Analysis for Proposed Revised 2012 Aggregate Production Quotas

DEA now proposes to adjust the established 2012 aggregate production quotas for some schedule I and II controlled substances. In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13. DEA proposes the adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances by considering (1) changes in demand for the class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3)

whether any increased demand can be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Administrator finds relevant.

In determining whether to propose adjustments to the 2012 aggregate production quotas, DEA considered updated information obtained from 2011 year-end inventories, 2011 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas had been established. The Deputy Administrator, therefore, proposes to adjust the 2012 aggregate production quotas for some schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

Basic Class – Schedule I	Previously Established 2012 Quotas	Proposed Adjusted 2012 Quotas
1-[1-(2-Thienyl)cyclohexyl]piperidine	0 g	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g	No Change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g	No Change
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No Change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g	No Change
2,5-Dimethoxyamphetamine	2 g	12 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g	12 g
3-Methylfentanyl	2 g	No Change
3-Methylthiofentanyl	2 g	No Change
3,4-Methylenedioxyamphetamine (MDA)	22 g	30 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	8 g	12 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g	24 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g	30 g
3,4-Methylenedioxypyrovalerone (MDPV)	8 g	12 g

3,4,5-Trimethoxyamphetamine	2 g	12 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	12 g
4-Methoxyamphetamine	77 g	88 g
4-Methylaminorex	2 g	12 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	12 g
4-Methyl-N-methylcathinone (mephedrone)	8 g	12 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g	No Change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g	No Change
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	12 g
5-Methoxy-N,N-diisopropyltryptamine	2 g	12 g
Acetyl-alpha-methylfentanyl	2 g	No Change
Acetyldihydrocodeine	2 g	No Change
Acetylmethadol	2 g	No Change
Allylprodine	2 g	No Change
Alphacetylmethadol	2 g	No Change
Alpha-ethyltryptamine	2 g	12 g
Alphameprodine	2 g	No Change
Alphamethadol	2 g	No Change
Alpha-methylfentanyl	2 g	No Change
Alpha-methylthiofentanyl	2 g	No Change
Alpha-methyltryptamine (AMT)	2 g	12 g
Aminorex	2 g	12 g
Benzylmorphine	2 g	No Change
Betacetylmethadol	2 g	No Change
Beta-hydroxy-3-methylfentanyl	2 g	No Change
Beta-hydroxyfentanyl	2 g	No Change
Betameprodine	2 g	No Change
Betamethadol	2 g	No Change
Betaprodine	2 g	No Change
Bufotenine	3 g	No Change
Cathinone	4 g	12 g
Codeine-N-oxide	602 g	No Change
Diethyltryptamine	2 g	12 g
Difenoxin	50 g	No Change
Dihydromorphine	3,608,000 g	No Change
Dimethyltryptamine	7 g	18 g
Gamma-hydroxybutyric acid	47,000,000 g	No Change
Heroin	20 g	No Change
Hydromorphinol	54 g	No Change
Hydroxypethidine	2 g	No Change
Ibogaine	5 g	No Change
Lysergic acid diethylamide (LSD)	16 g	No Change

Marihuana	21,000 g	No Change
Mescaline	5 g	13 g
Methaqualone	10 g	No Change
Methcathinone	4 g	12 g
Methyldihydromorphine	2 g	No Change
Morphine-N-oxide	655 g	No Change
N-Benzylpiperazine	2 g	12 g
N,N-Dimethylamphetamine	2 g	12 g
N-Ethylamphetamine	2 g	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	12 g
Noracymethadol	2 g	No Change
Norlevorphanol	52 g	No Change
Normethadone	2 g	No Change
Normorphine	18 g	No Change
Para-fluorofentanyl	2 g	No Change
Phenomorphan	2 g	No Change
Pholcodine	2 g	No Change
Properidine	2 g	No Change
Psilocybin	2 g	No Change
Psilocyn	2 g	No Change
Tetrahydrocannabinols	393,000 g	No Change
Thiofentanyl	2 g	No Change
Tilidine	10 g	No Change
Trimeperidine	2 g	No Change

Basic Class – Schedule II	Previously Established 2012 Quotas	Proposed Adjusted 2012 Quotas
1-Phenylcyclohexylamine	2 g	No Change
1-Piperdinocyclohexanecarbonitrile	2 g	27 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g	No Change
Alfentanil	15,000 g	19,550 g
Alphaprodine	2 g	No Change
Amobarbital	40,007 g	No Change
Amphetamine (for conversion)	8,500,000 g	No Change
Amphetamine (for sale)*	25,300,000 g	33,400,000 g
* DEA has determined that the revised total quantity 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 stock is 29,400,000 g. DEA has further determined that an additional 4,000,000 g is necessary to provide for future research and development needs and unexpected emergencies that could affect market availability.		
Carfentanil	0 g	5 g

Cocaine	216,000 g	No Change
Codeine (for conversion)	65,000,000 g	No Change
Codeine (for sale)	39,605,000 g	No Change
Dextropropoxyphene	7 g	No Change
Dihydrocodeine	400,000 g	No Change
Diphenoxylate	900,000 g	No Change
Ecgonine	83,000 g	No Change
Ethylmorphine	2 g	No Change
Fentanyl	1,428,000 g	No Change
Glutethimide	2 g	No Change
Hydrocodone (for sale)	59,000,000 g	63,000,000 g
Hydromorphone	3,455,000 g	3,628,000 g
Isomethadone	4 g	No Change
Levo-alphacetylmethadol (LAAM)	3 g	No Change
Levomethorphan	5 g	No Change
Levorphanol	3,600 g	No Change
Lisdexamfetamine	12,000,000 g	No Change
Meperidine	5,500,000 g	No Change
Meperidine Intermediate-A	5 g	No Change
Meperidine Intermediate-B	9 g	No Change
Meperidine Intermediate-C	5 g	No Change
Metazocine	5 g	No Change
Methadone (for sale)	20,000,000 g	No Change
Methadone Intermediate	26,000,000 g	No Change
Methamphetamine	3,130,000 g	No Change
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product**;** 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	56,000,000 g	No Change
Morphine (for conversion)	83,000,000 g	No Change
Morphine (for sale)	39,000,000 g	No Change
Nabilone	20,502 g	No Change
Noroxymorphone (for conversion)	7,200,000 g	No Change
Noroxymorphone (for sale)	401,000 g	1,981,000 g
Opium (powder)	63,000 g	73,000 g
Opium (tincture)	1,000,000 g	No Change
Oripavine	9,800,000 g	15,300,000 g
Oxycodone (for conversion)	5,600,000 g	No Change
Oxycodone (for sale)	98,000,000 g	98,700,000 g
Oxymorphone (for conversion)	12,800,000 g	No Change
Oxymorphone (for sale)	5,500,000 g	No Change
Pentobarbital	34,000,000 g	No Change
Phenazocine	5 g	No Change

Phencyclidine	24 g	No Change
Phenmetrazine	2 g	No Change
Phenylacetone	16,000,000 g	No Change
Racemethorphan	2 g	No Change
Remifentanil	2,500 g	No Change
Secobarbital	336,002 g	No Change
Sufentanil	5,000 g	No Change
Tapentadol	5,400,000 g	No Change
Thebaine	116,000,000 g	No Change

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 Part 1303, the Deputy Administrator may adjust the 2012 aggregate production quotas and individual manufacturing quotas allocated for the year.

Comments

Pursuant to 21 CFR 1303.11 and 1303.13, 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 determining any adjustment of the aggregate production quota.

Dated:

June 28, 2012

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Michele M. Leonhart
Administrator

[FR Doc. 2012-16396 Filed 07/03/2012 at 8:45 am; Publication Date: 07/05/2012]