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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA 358E]

Controlled Substances: Established Aggregate Production Quotas for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2012 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled Substances Act (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 2012 aggregate production quotas represent those quantities of Schedule I and II controlled substances that may be produced in the United States in 2012 to provide adequate supplies of each substance for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. 21 U.S.C. 826(a) and 21 CFR 1303.11. These quotas do not include imports of

controlled substances for use in industrial processes.

On October 21, 2011, a notice entitled "Controlled Substances: Proposed Aggregate Production Quotas for 2012" was published in the Federal Register (76 FR 65537). That notice proposed the 2012 aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. All interested persons were invited to comment on or object to the proposed aggregate production quotas on or before November 21, 2011.

Sixteen responses (eleven from DEA registered manufacturers, and five from other members of the public) were received within the published comment period, offering comments on a total of 37 Schedule I and II controlled substances. Several comments discussed the national prescription drug abuse epidemic and urged DEA to reduce quotas for prescription painkillers and opioids. Addressing prescription drug abuse requires a multi-faceted approach which includes education, treatment, and enforcement.

The quota system is specifically designed to operate within the statutory framework of the CSA, in conjunction with other controls to enable DEA to monitor the movement of controlled substances and certain chemicals into and through the closed system of distribution to help prevent diversion of such substances into the illicit market. Through the quota system, DEA limits the amount of those substances and chemicals manufactured each year to those quantities that will provide for the estimated medical, scientific, research, and industrial needs, lawful export requirements, and the establishment and maintenance of reserve stocks for the United States. All aspects of the closed system of distribution must work together to reduce or eliminate the diversion of controlled substances.

Other commenters stated that the proposed aggregate production quotas for alfentanil,

amphetamine (for sale), codeine (for conversion), codeine (for sale), dihydrocodeine, dihydromorphine, diphenoxylate, hydrocodone (for sale), hydromorphinol, levorphanol, lisdexamfetamine, meperidine, meperidine intermediate A, meperidine intermediate B, meperidine intermediate C, methadone, methadone intermediate, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), morphine-N-oxide, nabilone, noroxymorphone (for conversion), noroxymorphone (for sale), opium (tincture), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), pentobarbital, phenylacetone, properidine, sufentanil, tapentadol, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

In determining the aggregate production quotas, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11(b), in accordance with 21 U.S.C. 826(a) and other relevant factors, including the consideration of 2011 manufacturing quotas, current 2011 sales and inventories, 2012 export requirements, additional applications for quotas, as well as information on research and product development requirements. Based on this information, DEA determined that adjustments to the proposed aggregate production quotas for alfentanil, dihydrocodeine, diphenoxylate, hydromorphinol, lisdexamfetamine, meperidine, meperidine intermediate A, meperidine intermediate B, meperidine intermediate C, morphine-N-oxide, nabilone, pentobarbital, phenylacetone, properidine, and tapentadol are warranted. This notice reflects those adjustments.

When DEA published the Proposed Aggregate Production Quotas for 2012 on October 21, 2011, that notice proposed that all Schedule I and II controlled substances included

in 21 CFR 1308.11 and 1308.21 but not specifically referenced in that notice be established at zero. That reference extended to the three synthetic cathinones (4-methyl-N-methylcathinone; 3,4-methylenedioxy-N-methylcathinone; and 3,4,methylenedioxypyrovalerone) that were temporarily placed in Schedule I pursuant to the final order also published on October 21, 2011, at 76 FR 65371. No comments were received within the published comment period regarding the proposed quota for the three synthetic cathinones, however, DEA has determined, based on the information described above, that an increase from the proposed quota of zero is warranted for all three substances. This notice reflects those adjustments.

Regarding amphetamine (for sale), codeine (for conversion), codeine (for sale), dihydromorphine, hydrocodone (for sale), levorphanol, methadone, methadone intermediate, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), opium (tincture), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), sufentanil, and thebaine, DEA has determined that the proposed initial 2012 aggregate production quotas are sufficient to meet the current 2012 estimated medical, scientific, research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

In accordance with 21 U.S.C. 826 and 21 CFR 1303.11, the Administrator hereby determines that the 2012 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Established 2012 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-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	8 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4-Methylenedioxypyrovalerone (MDPV)	8g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
4-Methyl-N-methylcathinone (mephedrone)	8 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g

Bufotenine	3 g
Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	47,000,000 g
Heroin	20 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2012 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g

Alfentanil	15,000 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	8,500,000 g
Amphetamine (for sale)	25,300,000 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	400,000 g
Diphenoxylate	900,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	59,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	4 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	3,600 g
Lisdexamfetamine	12,000,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	5 g
Meperidine Intermediate-B	9 g
Meperidine Intermediate-C	5 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[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
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	20,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	401,000 g
Opium (powder)	63,000 g
Opium (tincture)	1,000,000 g
Oripavine	9,800,000 g
Oxycodone (for conversion)	5,600,000 g

Oxycodone (for sale)	98,000,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	5,500,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g
Phencyclidine	24g
Phenmetrazine	2 g
Phenylacetone	16,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	5,000 g
Tapentadol	5,400,000 g
Thebaine	116,000,000 g

The Administrator further determines 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. All aggregate production quotas are subject to adjustment pursuant to 21 CFR 1303.13.

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Dated:
December 8, 2011

Michele M. Leonhart
Administrator

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