

to groundwater at the Site, including a Remedial Investigation/Feasibility Study and the selection of a remedy for contaminated groundwater at the Site. In exchange for the City's payment, the City will receive from the United States a covenant not to sue or to take administrative action pursuant to Sections 106 or 107 of CERCLA, 42 U.S.C. 9606 and 9607, as amended, for the performance of response actions at the Site and the United States' past and future response costs at the Site. In addition, the City will dismiss its CERCLA claims against the Forest Service. The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Acting Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to pubcomment-ees.enrd@usdoj.gov or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States of America v. El Dorado County, California, et al.*, Civil No. S-01-1520 MCE GGH (E.D. Cal.) (DOJ Ref. No. 90-11-3-06554)(Consent Decree with City).

The Consent Decree with the City may be examined at U.S. Department of Agriculture, Office of General Counsel, 33 New Montgomery Street, 17th Floor, San Francisco, CA 94150 (contact Rose Mikovsky, (415) 744-3158). During the public comment period, the Consent Decree with the District may also be examined on the following Department of Justice Web site, http://www.usdoj.gov/enrd/Consent_Decrees.html. A copy of the Consent Decree with the City may also be obtained by mail from the Consent Decree Library, U.S. Department of Justice, P.O. Box 7611, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood (tonia.fleetwood@usdoj.gov), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please refer to *United States of America v. El Dorado County, California, et al.*, Civil No. S-01-1520 MCE GGH (E.D. Cal.) (DOJ Ref. No. 90-11-3-06554) (Consent Decree with City), and enclose a check in the amount of \$35.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that

amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-317F]

Controlled Substances: Final Revised Aggregate Production Quotas for 2009

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of final aggregate production quotas for 2009.

SUMMARY: This notice establishes final 2009 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA). The DEA has taken into consideration comments received in response to a notice of the proposed revised aggregate production quotas for 2009 published July 23, 2009 (74 FR 36511).

DATES: *Effective Date:* October 21, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: 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 28 CFR 0.104.

The 2009 aggregate production quotas represent those quantities of controlled substances in schedules I and II that may be produced in the United States in 2009 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.

On July 23, 2009, a notice of the proposed revised 2009 aggregate production quotas for certain controlled

substances in schedules I and II was published in the **Federal Register** (74 FR 36511). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before August 24, 2009.

Seven companies commented on a total of 18 schedules I and II controlled substances within the published comment period. Seven companies proposed that the aggregate production quotas for amphetamine (for sale), codeine (for conversion), dihydromorphine, fentanyl, hydrocodone (for sale), hydromorphone, lisdexamfetamine, methadone, methadone intermediate, methamphetamine (for sale), methylphenidate, nabilone, opium (tincture), oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale), phenylacetone, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has taken into consideration the above comments along with the relevant 2008 year-end inventories, initial 2009 manufacturing quotas, 2009 export requirements, actual and projected 2009 sales, research, product development requirements, and additional applications received. Based on this information, the DEA has adjusted the final 2009 aggregate production quotas for amphetamine (for conversion), dihydromorphine, hydrocodone (for sale), hydromorphone, lisdexamfetamine, morphine (for sale), opium (tincture), oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale), and phenylacetone to meet the legitimate needs of the United States.

Regarding amphetamine (for sale), codeine (for conversion), fentanyl, methadone, methadone intermediate, methamphetamine (for sale), methylphenidate, nabilone, and thebaine, the DEA has determined that the proposed revised 2009 aggregate production quotas are sufficient to meet the current 2009 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. § 826), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator, pursuant to 28 CFR 0.104, the Deputy Administrator hereby orders that the 2009 final aggregate production quotas for the following controlled substances,

expressed in grams of anhydrous acid or base, be established as follows:

Basic class—Schedule I	Final revised 2009 quotas
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	25 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g
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	27 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	5 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
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	3 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	3,132,000 g
Dimethyltryptamine	3 g
Gamma-hydroxybutyric acid	24,200,00 g
Heroin	20 g
Hydromorphanol	2 g
Hydroxypethidine	2 g
Ibogaine	1 g
Lysergic acid diethylamide (LSD)	10 g
Marihuana	4,500,000 g
Mescaline	7 g
Methaqualone	5 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	7 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	16 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	7 g
Psilocyn	7 g
Tetrahydrocannabinols	312,500 g
Thiofentanyl	2 g
Trimeperidine	2 g

Basic class—Schedule II	Final revised 2009 quotas
1-Phenylcyclohexylamine	2 g
1-Piperidinocyclohexanecarbonitrile	2 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	3 g
Amphetamine (for sale)	17,000,000 g
Amphetamine (for conversion)	7,500,000 g
Cocaine	247,000 g
Codeine (for sale)	39,605,000 g
Codeine (for conversion)	65,000,000 g
Dextropropoxyphene	106,000,000 g
Dihydrocodeine	1,200,000 g
Diphenoxylate	947,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	55,500,000 g
Hydromorphone	3,340,000 g
Isomethadone	2 g
Levo-alphaacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	8,200,000 g
Meperidine	8,600,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	1 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
Methylphenidate	50,000,000 g
Morphine (for sale)	36,300,000 g
Morphine (for conversion)	100,000,000 g
Nabilone	9,002 g
Noroxymorphone (for sale)	10,000 g
Noroxymorphone (for conversion)	9,000,000 g
Opium (powder)	230,000 g
Opium (tincture)	1,250,000 g
Oripavine	15,000,000 g
Oxycodone (for sale)	94,000,000 g
Oxycodone (for conversion)	4,500,000 g
Oxymorphone (for sale)	2,570,000 g
Oxymorphone (for conversion)	12,000,000 g
Pentobarbital	28,000,000 g
Phenazocine	1 g
Phencyclidine	20 g
Phenmetrazine	2 g
Phenylacetone	250,001 g
Racemethorphan	2 g
Remifentanyl	500 g
Secobarbital	67,000 g
Sufentanil	10,300 g
Thebaine	126,000,000 g

DEA proposed the aggregate production quota for tapentadol at 519,000 g in the 2009 proposed revised aggregate production quota notice published on July 23, 2009, in the **Federal Register** (74 FR 36511). Tapentadol is no longer listed because the material will be imported into the United States and not manufactured domestically.

The Deputy Administrator further orders that the aggregate production quotas for all other schedules I and II

controlled substances included in 21 CFR 1308.11 and 1308.12 shall be zero.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this

action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities, whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are

necessary to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: October 13, 2009.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA # 318E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2010.

SUMMARY: This notice establishes initial 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: *Effective Date:* October 21, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: 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 2010 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2010 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 May 21, 2009, a notice of the proposed initial 2010 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (74 FR 23881). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before June 22, 2009.

Twelve responses (eleven from DEA registered manufacturers, and one from a non-DEA registrant) were received within the published comment period, offering comments on a total of 28 schedule I and II controlled substances. One additional comment was received after the comment period ended and therefore was not considered. The commenters stated that the proposed aggregate production quotas for 3,4-methylenedioxyamphetamine, 3,4-methylenedioxyethylamphetamine, 3,4-methylenedioxyamphetamine, alfentanil, amphetamine (for sale), codeine (for sale), codeine (for conversion), dihydromorphine, fentanyl, gamma hydroxybutyric acid, hydrocodone, hydromorphone, isomethadone, levorphanol, lisdexamfetamine, methamphetamine (for sale), morphine (for conversion), nabilone, opium (tincture), oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale), remifentanil, sufentanil, tapentadol,

tetrahydrocannabinols, and thebaine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

In arriving at the aggregate production quotas, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11(b) and other relevant 2009 factors, including 2009 manufacturing quotas, current 2009 sales and inventories, 2010 export requirements, additional applications received, and research and product development requirements. Based on this information, DEA has adjusted the initial aggregate production quotas for 4-methoxyamphetamine, alpha-methyltryptamine, amphetamine (for conversion), dihydromorphine, isomethadone, levo-desoxyephedrine, lisdexamfetamine, lysergic acid diethylamide, methamphetamine (for sale), methamphetamine (for conversion), methaqualone, oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale) and phenylacetone to meet the legitimate needs of the United States.

DEA proposed the aggregate production quota for tapentadol at 519,000 g in the 2010 proposed initial aggregate production quota notice published on May 21, 2009 in the **Federal Register** (74 FR 23881). Tapentadol is no longer listed because the material will be imported into the United States and not manufactured domestically.

Regarding 3,4-methylenedioxyamphetamine, 3,4-methylenedioxyethylamphetamine, 3,4-methylenedioxyamphetamine, alfentanil, amphetamine (for sale), codeine (for sale), codeine (for conversion), fentanyl, gamma hydroxybutyric acid, hydrocodone, hydromorphone, levorphanol, morphine (for conversion), nabilone, opium (tincture), remifentanil, sufentanil, tetrahydrocannabinols, and thebaine DEA has determined that the proposed initial 2010 aggregate production quotas are sufficient to meet the current 2010 estimated medical, scientific, research and industrial needs of the United States.

Pursuant to 21 CFR 1303, the Deputy Administrator of DEA will, in 2010, adjust aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2009 year-end inventory and actual 2009 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.