Dated: December 17, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–307E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2008

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2008.

SUMMARY: This notice establishes initial 2008 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: December 27, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, 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 2008 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2008 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 August 24, 2007, a notice of the proposed initial 2008 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (72 FR 48683). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before September 14, 2007.

Seven responses were received resulting in comments on a total of 17 schedule I and II controlled substances within the published comment period. The commenters stated that the proposed aggregate production quotas for 14-hydroxymorphinone, alfentanil, amphetamine (for conversion), codeine (for sale), fentanyl, gamma hydroxybutyric acid, hydromorphone, lisdexamfetamine, marihuana, methadone, methylphenidate, noroxymorphone (for conversion), oxycodone, oxymorphone, sufentanil, tetrahydrocannabinols and thebaine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States for lawful export requirements and for the establishment and maintenance of reserve stocks. The DEA has determined that 14-hydroxymorphinone is considered a morphine derivative controlled under the morphine basic drug class code and therefore the comment received for 14-hydroxymorphinone was treated as a comment for morphine.

One commenter stated that, ''one or more manufacturers are preparing to receive Food and Drug Administration (FDA) approvals for generic version of Marinol. Generic versions of the drug, however, will not be approved for all of the indications for which FDA has found Marinol safe and effective. As a consequence, those newly approved generic versions should not be prescribed and distributed for all of the same indications as Marinol.'' The commenter further stated that if one of the generic Marinol manufacturers seeks an ''upwardly adjusted quota'' beyond that which is necessary for the medical requirements of the United States, then this would be contrary to the DEA's obligations under the Controlled Substances Act. For these reasons, the commenter requested a hearing regarding the aggregate production quota for tetrahydrocannabinols. The commenter believes that the approval of generic versions of Marinol will lead to an inappropriate increase in the ''medical use'' estimate for tetrahydrocannabinols in the United States. This is only one of the factors that DEA must consider when establishing the aggregate production quota. DEA must also consider the industrial and research requirements of the United States, lawful export requirements, and reserve stock requirements.

DEA notes it first established a 312,500 gram aggregate production quota for tetrahydrocannabinols in 2005 (70 FR 120, January 3, 2005). At that time, the increase from the proposed value of 211,000 grams was primarily due to an increase in the research and development efforts of DEA registered manufacturers, which included generic drug development efforts, increased drug requirements necessary to develop new indications of currently marketed drug products, and the development of novel drug delivery systems containing tetrahydrocannabinols. These research efforts continue today. Additionally, the FDA, which provides DEA with estimates of medical use of controlled substances each year, advised DEA that the medical use of Marinol is expected to grow by approximately 8.8 percent from 2006 to 2009. Export and industrial requirements are minimal and thus inconsequential to DEA's final analysis.

Pursuant to 21 CFR 1303.11(c), the DEA has determined that a hearing is not required in this matter. DEA has fully considered the comments received in connection with the hearing request within the context of the applications for manufacturing and procurement quotas received from DEA registered manufacturers and information provided by the FDA, and concludes that the amount proposed is sufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements and for the establishment and maintenance of reserve stocks. Therefore, DEA is establishing the 2008 aggregate production quota for tetrahydrocannabinols at the proposed value of 312,500 grams.

DEA has taken into consideration the above comments along with the relevant 2007 manufacturing quotas, current 2007 sales and inventories, 2008 export requirements, additional applications received, and research and product development requirements. Based on this information, the DEA has adjusted the initial aggregate production quotas for alfentanil, levorphanol, noroxymorphone (for sale), oxycodone (for conversion), and oxymorphone to meet the legitimate needs of the United States. The DEA also adjusted the initial aggregate production quota for hydrocodone due to known sales of hydrocodone products to companies that sell hydrocodone illegally through the Internet.

Regarding amphetamine (for conversion), codeine (for sale), fentanyl, gamma hydroxybutyric acid, hydromorphone, lisdexamfetamine, marihuana, methadone, methylphenidate, morphine, noroxymorphone (for conversion), oxycodone, sufentanil,

tetrahydrocannabinols and thebaine, the DEA has determined that the proposed initial 2008 aggregate production quotas are sufficient to meet the current 2008 estimated medical, scientific, research and industrial needs of the United States.

Pursuant to 21 CFR 1303, the Deputy Administrator of the DEA will, in 2008, adjust aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2007 year-end inventory and actual 2007 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.

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 2008 initial 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 initial 2008 quotas
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7)	10 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	20 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	7 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 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	3 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine	5 g
Aminorex	8 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	8 g
Cathinone	3 g
Codeine-N-oxide	302 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	2,549,000 g
Dimethyltryptamine	3 g
Gamma-hydroxybutyric acid	23,600,000 g
Heroin	5 g
Hydromorphinol	3,000 g
Hydroxypethidine	2 g
Ibogaine	1 g
Lysergic acid diethylamide (LSD)	61 g
Marihuana	4,500,000 g
Mescaline	2 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	310 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

Basic class—Schedule I	Established initial 2008 quotas
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	Established initial 2008 quotas
1-Phenylcyclohexylamine	2 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	3 g
Amphetamine (for sale)	17,000,000 g
Amphetamine (for conversion).	5,000,000 g
Cocaine	286,000 g
Codeine (for sale)	39,605,000 g
Codeine (for conversion)	59,000,000 g
Dextropropoxyphene	106,000,000 g
Dihydrocodeine	1,200,000 g
Diphenoxylate	828,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	45,200,000 g
Hydrocodone (for conversion)	1,500,000 g
Hydromorphone	3,300,000 g
Isomethadone	2 g
Levo-alphacetylmethadol (LAAM).	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	6,200,000 g
Meperidine	9,753,000 g
Metazocine	1 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[680,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,405,000 grams for methamphetamine mostly for conversion to a schedule III product; and 45,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000 g
Morphine (for sale)	35,000,000 g
Morphine (for conversion)	100,000,000 g
Nabilone	3,002 g
Noroxymorphone (for sale)	10,000 g
Noroxymorphone (for conversion).	8,000,000 g
Opium	1,400,000 g
Oxycodone (for sale)	70,000,000 g
Oxycodone (for conversion)	4,820,000 g
Oxymorphone	2,400,000 g
Oxymorphone (for conversion).	11,000,000 g
Pentobarbital	35,200,000 g
Phencyclidine	2,021 g
Phenmetrazine	2 g
Racemethorphan	2 g
Remifentanil	3,000 g
Secobarbital	2 g
Sufentanil	10,300 g
Thebaine	126,000,000 g

The Deputy Administrator further orders that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at 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: December 18, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–25113 Filed 12–26–07; 8:45 am]

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DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

December 19, 2007.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of the ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is