

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:
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& Chemical Evaluation Section, Drug
Enforcement Administration,
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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-hydroxymorphine, 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-
hydroxymorphine is considered a
morphine derivative controlled under
the morphine basic drug class code and
therefore the comment received for 14-
hydroxymorphine 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-alphaacetylmethadol (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
Remifentanyl	3,000 g
Secobarbital	2 g

Basic class—Schedule II	Established initial 2008 quotas
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.

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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