reproduction costs), payable to the U.S. Treasury.

Robert Maher,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–249R]

Controlled Substances: Proposed Revised Aggregate Production Quotas for 2004

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed revised 2004 aggregate production quotas.

SUMMARY: This notice proposes revised 2004 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before September 30, 2004.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–249'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCD. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/CCD, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent 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* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and 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 Section 0.100 of Title 28 of the Code of Federal Regulations. The Administrator in turn, has redelegated this function to the Deputy Administrator, pursuant to § 0.104 of Title 28 of the Code of Federal Regulations.

On December 15, 2003, DEA published a notice of established initial 2004 aggregate production quotas for certain controlled substances in Schedules I and II (68 FR 69720). This notice stipulated that the DEA would adjust the quotas in early 2004 as provided for in Part 1303 of Title 21 of the Code of Federal Regulations.

The proposed revised 2004 aggregate production quotas represent those quantities of controlled substances in Schedules I and II that may be produced in the United States in 2004 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. These quotas do not include imports of controlled substances for use in industrial processes.

The proposed revisions are based on a review of 2003 year-end inventories, 2003 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information available to the DEA.

Therefore, under the authority vested in the Attorney General by section 306 of the CSA of 1970 (21 U.S.C. 826), delegated to the Administrator of the DEA by § 0.100 of Title 28 of the Code of Federal Regulations, and redelegated to the Deputy Administrator pursuant to § 0.104 of Title 28 of the Code of Federal Regulations, the Deputy Administrator hereby proposes the following revised 2004 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base:

Basic class	Previously established initial 2004 quotas	Proposed revised 2004 quotas
Schedule I		
2,5-Dimethoxyamphetamine	3,501,000	3,501,000
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2	2
2,5-Dimethoxy-4-n-propylthiophenethylamine (2C–T-7)	10	10
3-Methylfentanyl	2	2
3-Methylthiofentanyl	2	2
3,4-Methylenedioxyamphetamine (MDA)	11	11
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	5	5
3,4-Methylenedioxymethamphetamine (MDMA)	16	16
3,4,5-Trimethoxyamphetamine	2	2
4-Bromo-2,5-Dimethoxyamphetamine (DOB)	2	2
4-Bromo-2,5-Dimethoxyphenethylamine (2–CB)	2	2
4-Methoxyamphetamine	2	2
4-Methylaminorex	2	2
4-Methyl-2,5-Dimethoxyamphetamine (DOM)	2	2
5-Methyoxy-3,4-Methylenedioxyamphetamine	2	2
5-Methoxy-N,N-diisopropyltryptamine (5–MeO-DIPT)	10	10
Acetyl-alpha-methylfentanyl	2	2
Acetyldihydrocodeine	2	2
Acetylmethadol	2	2
Allylprodine	4	4

Basic class	Previously established initial 2004 quotas	Proposed revised 2004 quotas
Alphacetylmethadol	2	2
Alpha-ethyltryptamine	2	2
Alphameprodine	2	2
Alphamethadol	3	3
Alpha-methyltryptamine (AMT)	10	10
Alpha-methylfentanyl	2	2
Alpha-methylthiofentanyl	2	2
Aminorex	2	2
Benzylmorphine	2	2
Betacetylmethadol	2	2
Beta-hydroxy-3-methylfentanyl	2	2
Beta-hydroxyfentanyl	2	2
Betameprodine	2	2
Betamethadol	2	2
Betaprodine	2	2
Bufotenine	2	2
Cathinone	2	2
Codeine-N-oxide	502	502
Diethyltryptamine	2	2
Difenoxin	9,000	8,000
Dihydromorphine	1,101,000	1,101,000
Dimethyltryptamine	3	3
Gamma-hydroxybutyric acid	10,000,000	8,000,000
Heroin	5	5
Hydromorphinol	2	2
Hydroxypethidine	2	2
Lysergic acid diethylamide (LSD)	61	61
Marihuana	840,000	840,020
Mescaline	2	2
Methaqualone	5	5
Methcathinone	4	4
Methyldihydromorphine	2	2
Morphine-N-oxide	502	502
N,N-Dimethylamphetamine	2	2
N-Ethyl-1-Phenylcyclohexylamine (PCE)	5	5
N-Ethylamphetamine	7	7
N-Hydroxy-3,4-Methylenedioxyamphetamine	2	2
Noracymethadol	2	2
Norlevorphanol	52	52
Normethadone	2	2
Normorphine	12	12
Para-fluorofentanyl	2	2
Phenomorphan	2	2
Pholcodine	2	2
Propiram	210,000	210,000
Psilocybin	2	2
Psilocyn	2	2
Tetrahydrocannabinols	176,000	176,000
Thiofentanyl	2	2
Trimeperidine	2	2
Schedule II		
1-Phenylcyclohexylamine	2	2
1-Piperidinocyclohexanecarbonitrile (PCC)	10	10
Alfentanil	2,000	2,000
Alphaprodine	2	2
Amobarbital	3	3
Amphetamine	10,987,000	12,700,000
Cocaine	186,000	200,000
Codeine (for sale)	41,341,000	41,341,000
Codeine (for conversion)	43,559,000	48,000,000
Dextropropoxyphene	167,365,000	167,365,000
Dihydrocodeine	776,000	776,000
Diphenoxylate	716,000	836,000
Ecgonine	38,000	38,000
Ethylmorphine	2	2
Fentanyl	970,000	1,225,000
Glutethimide	2	2
Hydrocodone (for sale)	30,622,000	34,000,000
Hydrocodone (for conversion)	1,500,000	1,500,000
Hydromorphone	1,651,000	1,651,000

Basic class	Previously established initial 2004 quotas	Proposed revised 2004 quotas
Isomethadone	2	2
Levo-alphacetylmethadol (LAAM)	2	2
Levomethorphan	2	2
Levorphanol	15,000	15,000
Meperidine	9,753,000	9,753,000
Metazocine	1	1
Methadone (for sale)	14,057,000	14,720,000
Methadone Intermediate	18,296,000	18,296,000
Methamphetamine	2,275,000	2,180,000
[675,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,475,000 grams for methamphetamine mostly for conversion to a Schedule III product; and 30,000 grams for methamphetamine (for sale)]		
Methylphenidate	23,726,000	27,428,000
Morphine (for sale)	21,800,000	25,000,000
Morphine (for conversion)	110,774,000	110,774,000
Nabilone	2	2
Noroxymorphone (for sale)	99,000	99,000
Noroxymorphone (for conversion)	3,800,000	3,800,000
Opium	1,000,000	1,300,000
Oxycodone (for sale)	41,606,000	49,200,000
Oxycodone (for conversion)	920,000	920,000
Oxymorphone	534,000	534,000
Pentobarbital	18,251,000	18,251,000
Phencyclidine	2,060	2,060
Phenmetrazine	2	2
Phenylacetone	11,000,000	11,000,000
Racemethorphan	2	2
Secobarbital	1,000	2
Sufentanil	4,000	4,000
Thebaine	59,437,000	72,400,000

The Deputy Administrator further proposes that aggregate production quotas for all other Schedules I and II controlled substances included in § 1308.11 and 1308.12 of Title 21 of the Code of Federal Regulations remain at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the **ADDRESSES** section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing as per 21 CFR 1303.13(c) and 1303.32.

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 not have a 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 $113,000,000 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: September 1, 2004.

Michele M. Leonhart,

Deputy Administrator.

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