## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–307R]**

### Controlled Substances: Proposed Revised Aggregate Production Quotas for 2008

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Notice of proposed revised 2008 aggregate production quotas.

**SUMMARY:** This notice proposes revised 2008 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 July 31, 2008.

**ADDRESSES:** To ensure proper handling of comments, please reference ''Docket No. DEA–307R'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to DEA Headquarters, Attention: DEA **Federal Register** Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* However, persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. 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, 8701 Morrissette Drive, Springfield, VA 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 to 28 CFR 0.104.

On August 24, 2007, a notice of proposed 2008 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (72 FR 48683). This notice stipulated that the DEA would adjust the quotas in early 2008 as provided for in 21 CFR part 1303.

The proposed revised 2008 aggregate production quotas represent those quantities of controlled substances in schedules I and II 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. These quotas do not include imports of controlled substances for use in industrial processes.

The proposed revisions are based on a review of 2007 year-end inventories, 2007 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 (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 proposes the following revised 2008 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base:

| Basic class—Schedule I | Previously established initial 2008 quotas | Proposed revised 2008 quotas |
|---|---|---|
| 2,5–Dimethoxyamphetamine | 2 g | 2 g |
| 2,5–Dimethoxy-4-ethylamphetamine (DOET) | 2 g | 2 g |
| 2,5–Dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7) | 10 g | 10 g |
| 3–Methylfentanyl | 2 g | 2 g |
| 3–Methylthiofentanyl | 2 g | 2 g |
| 3,4–Methylenedioxyamphetamine (MDA) | 20 g | 20 g |
| 3,4–Methylenedioxy-N-ethylamphetamine (MDEA) | 10 g | 10 g |
| 3,4–Methylenedioxymethamphetamine (MDMA) | 22 g | 22 g |
| 3,4,5–Trimethoxyamphetamine | 2 g | 2 g |
| 4–Bromo-2,5-dimethoxyamphetamine (DOB) | 2 g | 2 g |
| 4–Bromo-2,5-dimethoxyphenethylamine (2–CB) | 7 g | 7 g |
| 4–Methoxyamphetamine | 77 g | 77 g |
| 4–Methylaminorex | 2 g | 2 g |
| 4–Methyl-2,5-dimethoxyamphetamine (DOM) | 12 g | 12 g |
| 5–Methoxy-3,4-methylenedioxyamphetamine | 2 g | 2 g |
| 5–Methoxy-N,N-diisopropyltryptamine | 5 g | 5 g |
| Acetyl-alpha-methylfentanyl | 2 g | 2 g |
| Acetyldihydrocodeine | 2 g | 2 g |
| Acetylmethadol | 2 g | 2 g |
| Allylprodine | 2 g | 2 g |
| Alphacetylmethadol | 2 g | 2 g |
| Alpha-ethyltryptamine | 2 g | 2 g |
| Alphameprodine | 2 g | 2 g |
| Alphamethadol | 3 g | 3 g |
| Alpha-methylfentanyl | 2 g | 2 g |
| Alpha-methylthiofentanyl | 2 g | 2 g |
| Alpha-methyltryptamine | 5 g | 5 g |
| Aminorex | 8 g | 8 g |
| Benzylmorphine | 2 g | 2 g |
| Betacetylmethadol | 2 g | 2 g |
| Beta-hydroxy-3-methylfentanyl | 2 g | 2 g |
| Beta-hydroxyfentanyl | 2 g | 2 g |

| Basic class—Schedule I | Previously established initial 2008 quotas | Proposed revised 2008 quotas |
|---|---|---|
| Betameprodine | 2 g | 2 g |
| Betamethadol | 2 g | 2 g |
| Betaprodine | 2 g | 2 g |
| Bufotenine | 8 g | 8 g |
| Cathinone | 3 g | 3 g |
| Codeine-N-oxide | 302 g | 302 g |
| Diethyltryptamine | 2 g | 2 g |
| Difenoxin | 50 g | 50 g |
| Dihydromorphine | 2,549,000 g | 2,549,000 g |
| Dimethyltryptamine | 3 g | 3 g |
| Gamma-hydroxybutyric acid | 23,600,000 g | 21,940,000 g |
| Heroin | 5 g | 5 g |
| Hydromorphinol | 3,000 g | 3,000 g |
| Hydroxypethidine | 2 g | 2 g |
| Ibogaine | 1 g | 1 g |
| Lysergic acid diethylamide (LSD) | 61 g | 61 g |
| Marihuana | 4,500,000 g | 4,500,000 g |
| Mescaline | 2 g | 2 g |
| Methaqualone | 10 g | 10 g |
| Methcathinone | 4 g | 4 g |
| Methyldihydromorphine | 2 g | 2 g |
| Morphine-N-oxide | 310 g | 310 g |
| N,N-Dimethylamphetamine | 7 g | 7 g |
| N-Ethylamphetamine | 2 g | 2 g |
| N-Hydroxy-3,4-methylenedioxyamphetamine | 2 g | 2 g |
| Noracymethadol | 2 g | 2 g |
| Norlevorphanol | 52 g | 52 g |
| Normethadone | 2 g | 2 g |
| Normorphine | 16 g | 16 g |
| Para-fluorofentanyl | 2 g | 2 g |
| Phenomorphan | 2 g | 2 g |
| Pholcodine | 2 g | 2 g |
| Psilocybin | 7 g | 7 g |
| Psilocyn | 7 g | 7 g |
| Tetrahydrocannabinols | 312,500 g | 312,500 g |
| Thiofentanyl | 2 g | 2 g |
| Trimeperidine | 2 g | 2 g |

| Basic class—Schedule II | Previously established initial 2008 quotas | Proposed revised 2008 quotas |
|---|---|---|
| 1–Phenylcyclohexylamine | 2 g | 2 g |
| Alfentanil | 8,000 g | 8,000 g |
| Alphaprodine | 2 g | 2 g |
| Amobarbital | 3 g | 3 g |
| Amphetamine (for sale) | 17,000,000 g | 17,000,000 g |
| Amphetamine (for conversion) | 5,000,000 g | 5,000,000 g |
| Cocaine | 286,000 g | 247,000 g |
| Codeine (for sale) | 39,605,000 g | 39,605,000 g |
| Codeine (for conversion) | 59,000,000 g | 59,000,000 g |
| Dextropropoxyphene | 106,000,000 g | 106,000,000 g |
| Dihydrocodeine | 1,200,000 g | 1,200,000 g |
| Diphenoxylate | 828,000 g | 680,000 g |
| Ecgonine | 83,000 g | 83,000 g |
| Ethylmorphine | 2 g | 2 g |
| Fentanyl | 1,428,000 g | 1,428,000 g |
| Glutethimide | 2 g | 2 g |
| Hydrocodone (for sale) | 45,200,000 g | 42,000,000 g |
| Hydrocodone (for conversion) | 1,500,000 g | 1,500,000 g |
| Hydromorphone | 3,300,000 g | 3,300,000 g |
| Isomethadone | 2 g | 2 g |
| Levo-alphacetylmethadol (LAAM) | 3 g | 3 g |
| Levomethorphan | 5 g | 5 g |
| Levorphanol | 10,000 g | 10,000 g |
| Lisdexamfetamine | 6,200,000 g | 6,200,000 g |
| Meperidine | 9,753,000 g | 8,600,000 g |
| Metazocine | 1 g | 1 g |
| Methadone (for sale) | 25,000,000 g | 25,000,000 g |
| Methadone Intermediate | 26,000,000 g | 26,000,000 g |
| Methamphetamine | 3,130,000 g | 3,130,000 g |

| Basic class—Schedule II | Previously established initial 2008 quotas | Proposed revised 2008 quotas |
|---|---|---|
| [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 | 50,000,000 g |
| Morphine (for sale) | 35,000,000 g | 35,000,000 g |
| Morphine (for conversion) | 100,000,000 g | 100,000,000 g |
| Nabilone | 3,002 g | 3,002 g |
| Noroxymorphone (for sale) | 10,000 g | 10,000 g |
| Noroxymorphone (for conversion) | 8,000,000 g | 8,000,000 g |
| Oripavine[1] | 0 g | 15,000,000 g |
| Opium | 1,400,000 g | 1,400,000 g |
| Oxycodone (for sale) | 70,000,000 g | 70,000,000 g |
| Oxycodone (for conversion) | 4,820,000 g | 4,820,000 g |
| Oxymorphone | 2,400,000 g | 2,000,000 g |
| Oxymorphone (for conversion) | 11,000,000 g | 11,000,000 g |
| Pentobarbital | 35,200,000 g | 28,000,000 g |
| Phencyclidine | 2,021 g | 2,021 g |
| Phenmetrazine | 2 g | 2 g |
| Racemethorphan | 2 g | 2 g |
| Remifentanil | 3,000 g | 410 g |
| Secobarbital | 2 g | 2 g |
| Sufentanil | 10,300 g | 10,300 g |
| Thebaine | 126,000,000 g | 126,000,000 g |

[1] On December 10, 2007, the Drug Enforcement Administration published a final rule establishing a new basic class: Oripavine (72 FR 69618). Prior to the final rule, oripavine was considered a thebaine derivative and hence, was included under the thebaine basic class.

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 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. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means.

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).

**Regulatory Certifications**

*Regulatory Flexibility Act*

The Deputy Administrator hereby certifies that this action will not have a significant economic impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601–612. 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 lawful 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.

*Executive Order 12866*

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

*Executive Order 13132*

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.

*Executive Order 12988*

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

*Unfunded Mandates Reform Act of 1995*

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 (adjusted for inflation) 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.

*Congressional Review Act*

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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: June 6, 2008.

**Michele M. Leonhart,**

*Deputy Administrator.*

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