registration to import a basic class of any controlled substance listed in schedule I or II are, and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: October 12, 2006.

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–300P]

Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2007: Proposed

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed year 2007 assessment of annual needs.

SUMMARY: This notice proposes initial year 2007 assessment of annual needs for certain List I chemicals in accordance with the Combat Methamphetamine Epidemic Act of 2005 (CMEA), enacted on March 9, 2006. The Act required DEA to establish production quotas and import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. This effort was done in order to prevent the illicit use of these three chemicals in the clandestine manufacture of methamphetamine. The enactment of the CMEA places additional regulatory controls upon the manufacture, distribution, importation and exportation of the three List I chemicals.

DATES: Comments or objections must be received on or before December 4, 2006.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–300P'' 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/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA **Federal Register** Representative/ODL, 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*. 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, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, by e-mail, *ode@dea.usdoj.gov* or by fax, (202) 353–1263.

SUPPLEMENTARY INFORMATION: Section 713 of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Pub. L. 109–177) (CMEA) amended section 306 of the Controlled Substances Act (CSA) (Title 21 United States Code (U.S.C.) § 826 ''Production quotas for controlled substances'') by adding ephedrine, pseudoephedrine, and phenylpropanolamine to existing language to read as follows: ''The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year 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.'' Further, § 715 of CMEA amended 21 U.S.C. § 952 ''Importation of controlled substances'' by adding the same List I chemicals to the existing language in paragraph (a), and by adding a new paragraph (d) to read as follows:

(a) Controlled substances in schedule I or II and narcotic drugs in schedule III, IV, or V; exceptions:

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of subchapter I of this chapter, or any narcotic drug in schedule III, IV, or V of subchapter I of this chapter, or ephedrine, pseudoephedrine, and phenylpropanolamine, except that—

(1) such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves, and of ephedrine, pseudoephedrine, and phenylpropanolamine, as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and * * *

(d)(1) With respect to a registrant under section 958 who is authorized under subsection (a)(1) to import ephedrine, pseudoephedrine, or phenylpropanolamine, at any time during the year the registrant may apply for an increase in the amount of such chemical that the registrant is authorized to import, and the Attorney General may approve the application if the Attorney General determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical.

Note: This excerpt of the amendment is published for the convenience of the reader. The official text is published at 21 U.S.C. 952(a) and (d)(1).

The responsibility for establishing the assessment of annual needs has been delegated to the Administrator of the DEA by § 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 the Code of Federal Regulations Title 28 § 0.104.

The proposed year 2007 assessment of annual needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and/or imported into the United States 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.

Calculation of the Assessment: Medical Needs of the United States for Ephedrine and Pseudoephedrine

Since the manufacture and importation of ephedrine, pseudoephedrine, and phenylpropanolamine have not been previously regulated through the establishment of an assessment of annual needs, the Drug Enforcement Administration obtained assistance from a private independent contractor, IMS Health Government Solutions (IMS), to develop the proposed initial estimate of the medical needs of the United States of ephedrine and pseudoephedrine.

IMS' estimates of medical needs for ephedrine and pseudoephedrine were derived from 2005 data that the company routinely collects and offers to customers in order to understand the pharmaceutical market. For this analysis, IMS utilized the following types of data: (1) Sales to retail establishments (including pharmacies), (2) sales by retail establishments to patients, and (3) medical insurance claims. IMS' estimates of medical needs were intended to encompass only those products containing either ephedrine or pseudoephedrine, whether requiring a

prescription or available over-the-counter (OTC). Its estimates of use encompassed those products containing ephedrine and pseudoephedrine which are lawfully marketed under the Food, Drug and Cosmetic Act.

Although no direct estimates for the assessment of annual needs are currently available, IMS utilized information from a variety of data sources to develop three independent measures (as described in the next paragraph). After each of the three independent measures were calculated for ephedrine and pseudoephedrine, IMS then took a weighted average of the three individual estimates in order to derive its final estimate which was then considered by DEA. The weighted average was determined based on IMS' confidence in each individual estimate such that estimates with less confidence were given less weight.

The first estimate was based upon product sales to retail outlets, from IMS' National Sales Perspective (NSP) service. This estimate was supplemented with information from: IMS' Drug Distribution Database (DDD) and National Prescription Audit (NPA), ACNielsen's Scantrack (ST) and Homescan (HS) services. The second estimate was based upon product sales to customers, from NPA, ST, and HS services, supplemented with information from DDD and NSP services. The third estimate was based upon patient prescription claims data from IMS' ReferencePoint (RP) database, supplemented with information from United States Census Bureau population estimates and IMS' National Disease and Therapeutic Index (NDTI), NSP, DDD, ST, and HS services. A copy of the IMS report may be obtained from DEA Diversion Web site at: *http://www.deadiversion.usdoj.gov*.

Based on the IMS report, DEA concluded that 3,800 kg of ephedrine and 350,700 kg of pseudoephedrine were required to meet the medical needs of the United States.

Calculation of the Assessment: Medical Needs of the United States for Phenylpropanolamine

DEA did not request that IMS determine the medical needs for phenylpropanolamine. In November 2000, the Food and Drug Administration (FDA) issued a public health warning for phenylpropanolamine and requested that all drug companies discontinue marketing products containing phenylpropanolamine due to the drug's association with risk for hemorrhagic stroke. In response to the FDA's warning, many companies voluntarily reformulated their products to exclude phenylpropanolamine. Subsequently, on December 22, 2005, FDA published a Notice of Proposed Rulemaking (70 FR 75988) to reclassify all over-the-counter nasal decongestants and weight control drug products containing phenylpropanolamine preparations from their previously proposed monograph status (Category 1) to nonmonograph (Category II). FDA concluded that drug products containing phenylpropanolamine cannot be generally recognized as safe and should no longer be available for over-the-counter use in humans. Therefore, for purposes of calculating the medical needs of the United States for phenylpropanolamine, DEA considered the drug's use in veterinary products only.

DEA obtained from the FDA a list of all companies that manufacture veterinary products containing phenylpropanolamine. DEA contacted each company and requested information relating to sales of their phenylpropanolamine-containing products. Based on this review, DEA concluded that 4,354 kg were required to meet the medical needs of the United States.

Calculation of the Assessment: Industrial Needs, Export and Inventory Requirements

After DEA considered the medical needs for ephedrine, pseudoephedrine and phenylpropanolamine (veterinary products), it then considered: (1) Industrial needs of the United States, (2) lawful export requirements, and (3) maintenance of reserve stocks to determine the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

In consideration of the industrial needs of the United States for these three chemicals, DEA considered the use of ephedrine for the domestic manufacture of pseudoephedrine in 2005 and the amount of phenylpropanolamine used for the domestic manufacture of amphetamine in 2005.

In consideration of the requirements for lawful export purposes for these three chemicals, DEA considered total 2005 exports as provided on the DEA-Form 486 entitled ''Import/Export Declaration—Precursors and Essential Chemicals.'' Exports reported on the DEA–486 were as follows:

List I chemicals	2005 export quantity (kg)
Ephedrine	2,540
Pseudoephedrine	90,260
Phenylpropanolamine	320

In consideration of the amounts required for the maintenance of reserve stocks, DEA considered 20% of the estimated medical and industrial requirements.

Based on this information, the Deputy Administrator hereby proposes that the year 2007 assessment of annual needs for the following List I chemicals, expressed in kilograms of anhydrous base or acid, be established as follows:

List I chemicals	Proposed year 2007 quotas (kg)
Ephedrine (for sale)	7,100 kg
Ephedrine (for conversion)	128,760 kg
Pseudoephedrine (for sale)	511,100 kg
Phenylpropanolamine (for sale)	5,545 kg
Phenylpropanolamine (for conversion)	6,240 kg

Ephedrine (for conversion) refers to the industrial use of ephedrine, i.e., that which will be converted to pseudoephedrine. Phenylpropanolamine (for conversion) refers to the industrial use of phenylpropanolamine, *i.e.*, that which will be converted to amphetamine by the pharmaceutical industry. The ''for sale'' quotas refer to the amount of ephedrine, pseudoephedrine, and phenylpropanolamine used for purposes outside of the above-mentioned conversions.

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 chemicals 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.

The Office of Management and Budget has determined that notices of 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 any 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 quotas for ephedrine, pseudoephedrine, and phenylpropanolamine is mandated by law. 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 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 §§ 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 $118,000,000 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 § 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: October 13, 2006.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–270F]

Controlled Substances: Final Revised Aggregate Production Quotas for 2006

AGENCY: Drug Enforcement Administration (DEA), U.S. Department of Justice.

ACTION: Notice of final aggregate production quotas for 2006.

SUMMARY: This notice establishes final 2006 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act of 1970 (CSA). The DEA has taken into consideration comments received in response to a notice of the proposed revised aggregate production quotas for 2006 published July 5, 2006 (71 FR 38174).

EFFECTIVE DATE: October 19, 2006.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (Title 21 United States Code (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 Code of Federal Regulations (CFR) 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The 2006 aggregate production quotas represent those quantities of controlled substances in Schedules I and II that may be produced in the United States in 2006 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 5, 2006, a notice of the proposed revised 2006 aggregate production quotas for certain controlled substances in Schedules I and II was published in the **Federal Register** (71 FR 38174). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before July 26, 2006.

Eight companies commented on a total of 22 Schedules I and II controlled substances within the published comment period. Eight companies proposed that the aggregate production quotas for alfentanil, amphetamine, codeine (for conversion), dihydrocodeine, dihydromorphine, diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydrocodone, hydromorphinol, hydromorphone, methadone, methylphenidate, morphine (for conversion), N,N-dimethylamphetamine, opium, oxycodone, oxycodone (for conversion), oxymorphone, oxymorphone (for conversion), 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.

DEA has taken into consideration the above comments along with the relevant 2005 year-end inventories, initial 2006 manufacturing quotas, 2006 export requirements, actual and projected 2006 sales, research, product development requirements and additional applications received. Based on this information, the DEA has adjusted the final 2006 aggregate production quotas for alfentanil, codeine (for conversion), dextropropoxyphene, dihydromorphine, hydrocodone, hydromorphone, morphine (for conversion), N,N-dimethylamphetamine, opium, oxycodone, oxycodone (for conversion), oxymorphone, oxymorphone (for conversion), tetrahydrocannabinols, and thebaine to meet the legitimate needs of the United States.

Regarding amphetamine, dihydrocodeine, diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydromorphinol, methadone, and methylphenidate, the DEA has determined that the proposed revised 2006 aggregate production quotas are sufficient to meet the current 2006 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 2006 final aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows: