

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 (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.

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: September 13, 2007.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-306P]

#### Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008: Proposed

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

**ACTION:** Notice of proposed annual assessment of needs for 2008.

**SUMMARY:** This notice proposes the initial year 2008 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 was done 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:** Written comments or objections must be postmarked, and electronic comments must be sent, on or before October 11, 2007.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-306" 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](mailto: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, Telephone: (202) 307-7183.

**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) (21 U.S.C. section 826) 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, section 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.

**Editor's 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 28 CFR section 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR section 0.104.

The proposed year 2008 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 chemical for: The estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks.

Pursuant to 21 CFR part 1315, the Deputy Administrator of the DEA will, in early 2008, adjust the assessment of annual needs and individual importing and manufacturing quotas allocated for the year based upon 2007 year-end inventory and actual 2007 disposition data supplied by quota recipients for ephedrine, pseudoephedrine, and phenylpropanolamine.

The Deputy Administrator hereby proposes that the year 2008 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 2008 assessment of annual needs [kg]
Ephedrine (for sale) .....	11,500
Ephedrine (for conversion) .....	128,760
Pseudoephedrine (for sale) .....	511,100
Phenylpropanolamine (for sale) .....	5,545
Phenylpropanolamine (for conversion) .....	85,470

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 drug products administered to patients with Acquired Immune Deficiency Syndrome and Attention Deficit Disorder. The "for sale" assessments refer to the amount of ephedrine, pseudoephedrine, and phenylpropanolamine intended for ultimate use in products containing these List I chemicals.

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 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. 601–612. The establishment of the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine is mandated by law.

The assessments 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. 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 (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.

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: September 13, 2007.

**Michele M. Leonhart,**  
Deputy Administrator.

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