Federal Register

Thursday,
September 20, 2007

Part VII

Department of Justice

Drug Enforcement Administration

Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2007 and 2008; Notices

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–300F]

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of assessment of annual needs for 2007.

SUMMARY: This notice establishes the 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.

DATES: *Effective Date:* September 20, 2007.

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

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Section 713 of the CMEA (Title VII of Pub. L 109–177) amended section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requiring that the Attorney General establish quotas to provide for the annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Further, section 715 of the CMEA amended 21 U.S.C. 952 by adding ephedrine, pseudoephedrine, and phenylpropanolamine to the existing language concerning importation of controlled substances.

The 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 in 2007 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.

This responsibility for establishing the assessment 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.

On October 19, 2006, a notice entitled, ''Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2007: Proposed'' was published in the **Federal Register** (71 FR 61801). This notice proposed the initial 2007 assessment of annual needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the proposed assessments on or before December 4, 2006.

Comments Received

DEA received eight comments from five interested parties during the comment period. Two comments were received from two DEA registered chemical importers; one comment was received from a DEA registered chemical manufacturer; two comments were received from an association representing over-the-counter (OTC) manufacturers, distributors and retailers; and three comments were received from a law firm representing an OTC product manufacturer. After the comment period closed, DEA received an additional comment from the above-mentioned association. All comments received during the comment period are summarized here and discussed further below.

One of the five commenters supported the DEA's proposal. This commenter, one of the DEA registered chemical importers, stated that DEA's proposed assessment of annual needs for pseudoephedrine and ephedrine was ''reasonable.'' Additionally, the commenter requested that the DEA consider providing ''regulatory relief'' with regard to the new import provisions by minimizing the amount of information that will be required on the import applications and relying more heavily on the requirements under the ''spot market'' provision to ensure that these substances are imported for legitimate needs. Since the information collected as part of the quota provisions and import applications is not the subject of this notice, the latter part of this comment was not considered by DEA.

Three of the five commenters raised concerns regarding DEA's proposal. Two of these commenters raised concerns regarding the assessment for ephedrine while one raised concerns regarding the assessment for phenylpropanolamine (for conversion). These commenters included a DEA-registered manufacturer that imports phenylpropanolamine, an association representing OTC manufacturers, distributors, and retailers, and a law firm representing an OTC product manufacturer.

The fifth commenter requested that DEA consider its proposed individual requirement for ephedrine in fixing the final assessment of annual needs.

DEA did not receive any comments on its proposed assessment of annual needs for ephedrine (for conversion) and phenylpropanolamine (for sale) and is therefore finalizing these values as proposed. The assessment of annual needs for phenylpropanolamine (for conversion), ephedrine (for sale) and pseudoephedrine (for sale) are discussed below within the context of the comments received.

Comments Regarding DEA's Proposed Assessment for Phenylpropanolamine (for Conversion)

One commenter, a manufacturer that imports phenylpropanolamine, considered the proposed phenylpropanolamine (for conversion) assessment, i.e., the amount necessary for the manufacture of other substances, insufficient to meet its customers' needs. The commenter stated that phenylpropanolamine, and its isomers, are used as chiral agents in numerous chemical syntheses, a factor that the commenter believed DEA had not considered in its original proposal. The commenter stated that the synthesized drugs are used in drug products administered to patients with Acquired Immune Deficiency Syndrome (AIDS) and Attention Deficit Disorder (ADD). This commenter believed that these uses are probably the largest use of phenylpropanolamine.

DEA had considered in its proposal the amount of phenylpropanolamine it believed was necessary for the manufacture of ADD medicines, but had not considered the chemical's use in the manufacture of drugs utilized in the treatment of AIDS. After consideration of this comment along with additional information obtained by DEA in connection with this comment, DEA has adjusted its assessment for phenylpropanolamine (for conversion) from 6,240 kg to 85,470 kg.

Comments Regarding DEA's Proposed Assessments for Ephedrine (for Sale) and Pseudoephedrine (for Sale)

Two commenters, the association representing OTC manufacturers, distributors, and retailers, and the law firm representing an OTC product manufacturer, indicated their belief that the proposed ephedrine assessment was insufficient to meet market demands for ephedrine-containing OTC products. The association also questioned the

sufficiency of the assessment for pseudoephedrine.

The law firm representing an OTC product manufacturer submitted three individual comments during the comment period. The first comment requested a 30-day extension of the comment period. The commenter stated that they were unable to locate the IMS Health Government Solutions (IMS) report on the DEA Diversion Web site. The commenter was contacted by DEA and advised as to where the IMS report was located; upon locating the report, the commenter withdrew their request for a 30-day extension. The second comment was another request for a 30-day extension of the comment period deadline in order to compile and submit to DEA a report from ''* * * experts in medicine, economics, and DEA/law enforcement to assess the impact of the proposed quota on medical, industrial, scientific and other legitimate demand for the two chemical substances.'' The commenter submitted the report to DEA in its third comment. The commenter recommended ''withdrawal of the proposed 2007 assessment due to its inaccuracy and incompleteness.'' The commenter requested that DEA issue a new notice. The comment made the following conclusions: (1) That the IMS report was flawed because it excluded and underestimated ''legitimate demand for ephedrine sold in over-the-counter (OTC) drugs for respiratory ailments via convenience stores''; (2) ''The underestimation of legitimate medical need will lead to ephedrine quota levels beneath those necessary to ensure adequate supplies of ephedrine to treat respiratory ailments''; (3) ''The exclusion of convenience stores from the IMS calculus and any resulting deprivation of supply to satisfy legitimate demand in those stores will imperil the health and safety of Americans with respiratory ailments, resulting in increased hospitalization and possibly deaths due to a lack of ready access in moments of critical need''; (4) ''* * * the prejudicial exclusion of convenience store demand from the 2007 Annual Needs estimate not only reduces supply beneath safe levels but also creates an anti-competitive market bias in favor of pharmacies over convenience stores to the economic and physical detriment of all with legitimate medical needs.'' The commenter also stated that IMS did not conduct any ''sensitivity tests, assessments of bias, or estimates of precision related to use of surveys that are critical to estimates of certain segments of the legitimate medical use market, such as convenience stores.''

DEA notes that IMS completed a sensitivity analysis upon review of the comments submitted by this commenter. The results of this analysis and DEA's consideration of the results of that analysis are discussed below. IMS' final report is available on the Office of Diversion Control's Web site (*http://www.deadiversion.usdoj.gov*).

The association representing OTC manufacturers, distributors, and retailers provided two comments to the docket during the comment period. The commenter stated that the IMS report did not ''properly document data from the convenience store segment.'' The commenter noted its concern that DEA has ''narrowly defined 'medical need' '' for preparations containing these List I chemicals, specifically ephedrine. The commenter stated that it had commissioned ''a study by an outside economic consulting firm to provide the DEA with substantive information that would help DEA produce a more accurate and substantive estimate of ephedrine needs assessment for 2007.'' The comment included a request for an extension of time which was not granted. The study was submitted to both DEA and IMS after the comment period had closed.

In connection with the concerns raised by these two commenters that the preliminary IMS study did not adequately address sales of ephedrine-based OTC drug products through the convenience store channel of distribution, DEA notes that its contract with IMS had two distinct phases. Phase I, which was completed prior to publication of the proposed assessment of annual needs, involved a preliminary assessment of the medical use of ephedrine and pseudoephedrine and a written summary of the methodology it used to develop the estimates. This information was made available for review by the public when the DEA published the ''*Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2007: Proposed*'' (71 FR 61801). The second phase of DEA's contract involved IMS' development of a final estimate which was developed by IMS after consideration of all available information, including: comments received from the public during the comment period, the study submitted directly to IMS by the association representing OTC manufacturers, distributors and retailers, updated information from the data sources used by IMS to compile the initial estimates, and other available information on the sales of OTC drug products through various distribution channels. The final report is discussed below and is available on DEA's Office of Diversion Control Web site, *http://www.deadiversion.usdoj.gov.*

Report Prepared by IMS Health

As discussed in its October 19, 2006, proposed Assessment of Annual Needs, since the manufacture and importation of ephedrine, pseudoephedrine, and phenylpropanolamine were not previously regulated through the establishment of an assessment of annual needs, DEA obtained assistance from a private independent contractor, IMS, to develop the 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 data the company routinely collects and offers to customers 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. The estimates of use encompassed those products containing ephedrine and pseudoephedrine which are lawfully marketed under the Federal Food, Drug and Cosmetic Act. As noted previously, IMS did not examine estimates for phenylpropanolamine.

The CSA requires that DEA establish quotas for ephedrine, pseudoephedrine, and phenylpropanolamine to meet the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and maintenance of reserve stocks. Accordingly, DEA requested that IMS determine the amount of ephedrine and pseudoephedrine necessary to meet the estimated medical needs of the United States. DEA and IMS agreed that looking at sales of prescription and OTC drug products containing these list I chemicals through all distribution channels alone would not be an appropriate proxy from which to derive an estimate of what IMS describes in its report as the ''legitimate medical use'' because this approach would have the unwanted effect of including amounts of ephedrine and pseudoephedrine purchased for use in the clandestine manufacture of methamphetamine.

Therefore, IMS concluded that the best proxy for evaluating the estimated medical use for these chemicals, i.e., the alternate method that seeks to exclude

sales of ephedrine and pseudoephedrine-based products destined for clandestine methamphetamine production in the United States, would involve evaluating the changes (increases or decreases) in sales of prescription and OTC products containing these List I chemicals which have resulted from various state initiatives aimed at imposing restrictions on the retail sales of OTC drug products containing these chemicals. These state-sponsored initiatives began as early as 2004. The requirements vary from state to state, but examples include: (1) Placing OTC products behind pharmacy counters, (2) restricting the quantity of OTC drug products that could be purchased by individuals, and (3) providing proof of identification at the time of purchase. Based on this analysis, IMS concluded that the median changes in OTC sales of ephedrine products were: 23.7 percent increase through retail channels (mass merchandisers, grocery stores, etc.) and a 45.2 percent decrease in ''other'' distribution channels (including gas station and convenience stores). For comparison, sales of OTC products containing pseudoephedrine decreased by 22 percent through retail distribution channels and also decreased by 10.8 percent through other distribution channels. Accordingly, these changes, along with the changes observed in the usage of prescription drug products containing ephedrine and pseudoephedrine, were applied across all data systems used in the IMS analysis.

Based on the comments analyzed by IMS, IMS completed a sensitivity analysis of their final estimates. IMS concluded that the estimated medical use for pseudoephedrine was ''very stable * * * differing from the simple average of the component final estimates by at most 7.7%.'' By contrast, however, the estimated medical use for ephedrine was ''relatively unstable, as the sensitivity estimates differ from the final estimate by as much as 46.5%.''

IMS' Medical Need Estimate for Pseudoephedrine and the DEA's Final 2007 Assessment of Annual Needs for Pseudoephedrine (for Sale)

In its final report, IMS concluded that the estimated medical need for pseudoephedrine decreased in all three models analyzed. The initial IMS report estimated that the medical need in the United States for pseudoephedrine was 350,700 kg and in the final report the medical need estimate was 280,268 kg. The results of the sensitivity analysis suggest that the pseudoephedrine medical need assessment was very stable from the simple average of the three component final estimates and, at most, differed by 7.7 percent. The decrease observed in IMS final estimate as compared with the preliminary estimate was due to a necessary adjustment resulting from IMS initially expressing its estimate (350,700 kg) in terms of the compound weight, e.g., pseudoephedrine hydrochloride, rather than expressing its estimate in terms of the weight of the molecule pseudoephedrine alone. Overall, this resulted in a correction down in the IMS estimate by approximately 20 percent.

Although IMS' final estimate is lower, DEA has concluded that the amount proposed would allow for sufficient inventory allowances to DEA registered manufacturers and importers of pseudoephedrine products and could account for any unexpected change (increase) in the use of pseudoephedrine that may result from changes in the acceptability of phenylephrine as a substitute for pseudoephedrine in many OTC cough and cold products currently on the market.

IMS' Medical Need Estimate for Ephedrine and the DEA's Final 2007 Assessment of Annual Needs for Ephedrine (for Sale)

As with the pseudoephedrine estimate, IMS based its preliminary ephedrine medical need estimate on the weights of the salt forms of ephedrine; this resulted in a necessary adjustment down by 20 percent for its final medical need estimate. Unlike the pseudoephedrine estimate which decreased in the final report, IMS' analysis of the data available resulted in an increase from 3,800 kg to 4,096 kg. Furthermore, the results of its sensitivity analysis concluded that the 4,096 kg medical need estimate was ''unstable'' as compared to the estimate for pseudoephedrine and that the sensitivity estimates differed from the final estimate by as much as 46.5 percent (range was 4,096 kg to 5,998 kg). The two factors principally responsible for the 46.5 percent range were: (1) The incorporation of estimated amounts of OTC products sold in convenience stores, which IMS concluded to be 7.7 percent, and (2) the incorporation of ''non-matched products,'' i.e., those products not originally confirmed to contain ephedrine or pseudoephedrine, into IMS' estimate.

Based on this analysis, DEA concludes that the proposed assessment of annual needs for ephedrine (for sale) was inadequate to meet the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and maintenance of reserve stocks. After considering IMS' final estimate of the medical need of ephedrine-based prescription and OTC products (5,998 kg), along with information DEA collects from DEA registered chemical exporters (through the DEA–486 Import/Export Declaration for Listed Chemicals), and amounts necessary to maintain reserve stocks, DEA has increased the ephedrine (for sale) assessment from 7,100 kg to 11,500 kg.

Conclusion

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 section 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR section 0.104, the Deputy Administrator hereby orders that the 2007 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, be established as follows:

List I chemicals	Final year 2007 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

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. 601–612. The establishment of assessments of annual needs for 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.

[FR Doc. E7–18523 Filed 9–19–07; 8:45 am]

BILLING CODE 4410–09–P

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.* 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