Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than February 25, 2008.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–25048 Filed 12–26–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on November 15, 2007, Organix Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Cocaine (9041)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers for research purposes.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than February 25, 2008.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–25114 Filed 12–26–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–306E]

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Assessment of Annual Needs for 2008.

SUMMARY: This notice establishes 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.

EFFECTIVE DATE: December 27, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, 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 Combat Methamphetamine Epidemic Act of 2005 (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. 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 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 in 2008 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.

The responsibility for establishing the assessment 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 September 20, 2007, a notice entitled, ''Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008: Proposed'' was published in the **Federal Register** (72 FR 53911). This notice proposed the initial 2008 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 October 11, 2007.

Comments Received

DEA did not receive any comments or objections from the more than 1,050 DEA-registered manufacturers and importers directly impacted by this notice. However, DEA did receive one comment from a law firm representing a DEA-registered distributor of nonprescription (over-the-counter (OTC)) products containing ephedrine, pseudoephedrine, or phenylpropanolamine. When sold at retail, these products are referred to as scheduled listed chemical products.[1] This same commenter commented to DEA's proposed 2007 Assessment of Annual Needs which was published in the **Federal Register** on October 19, 2006 (71 FR 61801). The comment submitted to this notice is virtually identical to that previously considered by DEA in that the comment included the same reports. However, DEA notes that the current comment includes one new report and one new letter. The new report was prepared by an economist who was retained by the DEA-registered distributor being represented by the law firm. The letter was prepared by the statistician whose report was submitted as part of this commenter's comments to the 2007 proposed assessment.

The commenter's comments related to DEA's proposed assessments for ephedrine (for sale) and pseudoephedrine (for sale). These assessments are discussed below within

[1] Title 21 U.S.C. 802(45) defines a scheduled listed chemical product as ''a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine; and * * * may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug.''

the context of the comment received. As DEA did not receive any comments on its proposed Assessment of Annual Needs for ephedrine (for conversion), phenylpropanolamine (for conversion), and phenylpropanolamine (for sale), DEA is finalizing these values as proposed.

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

The commenter indicated its belief that the proposed ephedrine assessment was insufficient to meet market demands for ephedrine-containing OTC products. The commenter also questioned the sufficiency of the assessment for pseudoephedrine. The commenter included in its comment a report from a statistician, a report from an economist, and a report from a physician to assess the impact of the proposed quota on medical, industrial, scientific and other legitimate demand for the two chemicals. The commenter's comments, and DEA's responses, are discussed below.

Economic Impact Analysis and Impact on Small Businesses

The commenter claimed that DEA underestimated the economic impact of the proposed quota limits. The commenter also claimed that DEA failed to consider the quota impact on small businesses. To support its claims, the commenter provided a new report from an economist. The commenter claimed that ''DEA has violated statutory requirements by relying on inaccurate and incomplete data to produce its economic impact.'' Based on the new report, the commenter asserted that the economic impact of DEA's proposal ''* * * will be a reduction of revenues of $2 billion dollars per year (from the effective ban on ephedrine product sales) and will result in the termination of 25–50 American workers' jobs per firm.''

DEA Response: The economic information submitted by the commenter in support of its claims is flawed. The commenter has made the fundamental mistake of assuming that its sales are representative of the industry as a whole, an assumption which broader industry numbers do not support. In addition, the commenter has overstated the number of convenience stores that are selling these products, which further magnifies the errors in its analyses. The commenter's estimates of the convenience store market for scheduled listed chemical products are shown in Table 1.

TABLE 1.—COMMENTER'S ESTIMATES OF ANNUAL VALUE OF THE EPHEDRINE MARKET

	Lower bound	Upper bound
Ephedrine	$166 million	$237 million.
Number of Convenience Stores Selling the Products*.	72,500.	

* Commenter did not provide an upper bound.

These numbers are at serious variance with the most comprehensive data available on sales of nonprescription medications (OTC drugs) at convenience and other nonconventional outlets and with estimates of the total size of the ephedrine market; nonconventional outlets include convenience stores, gas stations with convenience stores, gas stations without convenience stores, liquor stores, and novelty and gift stores. Conventional outlets include grocery stores, drug stores, discount stores, superstores and warehouse stores, and general merchandise stores. Internet and mail order stores are a third category. Table 2 presents data on the value of nonprescription medication sales at various retail sectors based on the 2002 Economic Census of the Retail Trade, Product Line, the most recent Census data. The table includes the number of establishments in the sector, the number of those establishments that sell nonprescription drugs, the value of nonprescription sales in the sector, and the value of all sales in drug, health, and beauty aids. Nonprescription drugs are a subset of the larger category; the value of the broader category is listed because it was used to derive an estimate of sales of nonprescription drugs for sectors whose sales the Census did not disaggregate. The final column lists the percentage of an establishment's sales that the Census reported nonprescription drugs represent for those establishments that sell the products.

TABLE 2.—CENSUS DATA ON PRODUCT LINE SALES BY SECTOR

[Thousand $]

Retail sector	Number of establishments	Number of establishments w/OTC drugs	OTC drug sales 2002	All drug, health, and beauty aids	OTC drugs as % of all sales
Grocery	66,150	26,029	$2,670,914	$35,172,224	1.3
Convenience Store	29,212	12,399	133,263	443,116	1.6
Specialty Food	24,485	194	2,551	24,045	1.6
Liquor Store	28,957	1,496	19,344	89,541	2
Drug and Personal Care	81,797	36,797	8,348,218	140,759,601	4.7
Gas Station with Convenience Store	93,691	*24,597	*248,082	824,904	***<0.4
Gas Station	27,755	*685	*7,488	70,577	***<0.1
Discount Store	5,650	2,079	1,439,227	22,025,430	1.1
Superstore + Club	2,912	2,758	2,270,530	21,066,107	1.2
Other general merchandise	28,546	11,840	167,951	3,357,825	1.2
Gift and novelty	35,795	*1,686	*47,973	159,515	***<1
Electronic and Mail Order	15,910	250	565,305	29,618,519	13
Total	440,860	120,810	15,920,846	253,611,404	.....

TABLE 2.—CENSUS DATA ON PRODUCT LINE SALES BY SECTOR—Continued

[Thousand $]

Retail sector	Number of establish-ments	Number of establish-ments w/OTC drugs	OTC drug sales 2002	All drug, health, and beauty aids	OTC drugs as % of all sales
All Nonconventional **	215,410	40,863	456,150	1,587,653	.....

* OTC sales not listed separately in Census data; OTC value estimated based on percentage of OTC to all drug, health, and beauty products sold at regular convenience stores (i.e., convenience stores that are not part of gas stations). Number of stores estimated using ratio of regular convenience stores that carry OTC to those that cover all drug, health, and beauty aids.

** Nonconventional outlets include convenience stores, gas stations with and without convenience stores, liquor stores, and novelty stores.

*** Percentage is the percentage that all drug, health, and beauty aid products sales represent of total sales; the nonprescription medications are a subset of these sales.

The nonconventional outlets—convenience stores, gas stations with and without convenience stores, novelty stores, and liquor stores—make up only about three percent of the total market for nonprescription drugs. Using A.C. Nielsen data [2] on the growth of the OTC market from 2002 to 2006 and the Census data on the value of the market, the annual value of nonprescription drug sales for nonconventional outlets in 2006 is estimated to be about $532 million and the total market for all retail sectors is about $18 billion.

Nonprescription drugs contain a wide range of medications. Data from the Consumer Healthcare Products Association and A.C. Nielsen indicate that cough and cold medications make up about 27 percent to 40 percent of the total OTC market, or about $4.8 billion to $7.3 billion in 2006 (other major groups include analgesics and heartburn medications).[3] The cough and cold medications include a variety of drugs, from cough syrups to antihistamines. Because there is no reason to believe that nonconventional outlets selling nonprescription drugs sell more or less cough or cold medications in proportion to other nonprescription drugs than any other retail outlet, it is reasonable to estimate that the total value of their sales for all cough and cold drugs in 2006 was approximately $142 million to $215 million (3 percent of the total), or somewhat less than the commenter estimated the market for ephedrine alone to be.

Ephedrine and pseudoephedrine constitute a subset of the cough and cold medication market. DEA has not been able to obtain any data on what percentage of the market they represent. In 2006, estimates of the retail value of products containing one of the chemicals that DEA and the Food and Drug Administration obtained from market researchers ranged from $500 million to $1.5 billion, but the estimates involved considerable uncertainty; the estimates were also based on the market before many manufacturers began to market new products that substituted phenylephrine for pseudoephedrine. Data from market research firm Information Resources, Inc. on the top 200 over-the-counter brands (including private label products) sold through grocery stores, drug stores, and mass market stores in 2006 indicate that at least 65 percent of the cough and cold medications do not contain pseudoephedrine; if private label products contain pseudoephedrine at the same rate as brand name products, at least 78 percent of the cough and cold medication sales do not contain pseudoephedrine.[4] No product in the top 200 appears to contain ephedrine; the sales value of the 200th product was about $20.4 million.

The cough and cold medication sector, as defined by A.C. Nielsen, includes a wide variety of tablets, gel capsules, liquids, and cough drops, many of which do not contain either ephedrine or pseudoephedrine. Even if the entire market sector consisted of scheduled listed chemical products, the estimates the commenter submitted and shown in Table 1 are clearly overstated.

Data developed by IMS Health Government Solutions for the Assessment of Annual Needs for 2007, [5] which used a range of industry sources, plus data from a confidential source, indicate that the ephedrine market is at most between 2 percent and 6.6 percent the size of the pseudoephedrine market (i.e., the value of sales of ephedrine products represent 2 percent to 6.6 percent of the value of sales of pseudoephedrine products). In a comment on a previous rule,[6] the commenter submitted estimates that implied that ephedrine sales at convenience stores to which it distributes were about 20 percent of the value of pseudoephedrine sales at convenience stores to which it distributes. Table 3 shows the commenter's implied size of the pseudoephedrine market at convenience stores.

[2] A.C. Nielsen data from Consumer Healthcare Products Association *(http://www.chpainfo.org/ChpaPortal/PressRoom/Statistics/OTCSalesbyCategory.htm)*.

[3] The A.C. Nielsen data were used to estimate only a ratio of the cough and cold medication to the total OTC medication market. The total value of the market was estimated based on the 2002 Census data inflated to 2006 dollars. The Nielsen data do not include Wal-Mart and may not include many convenience stores. In addition, the Nielsen data include a number of product lines that either are not nonprescription drugs (e.g., toothpaste) or mix nonprescription drugs and other products (e.g., first aid ointments and bandaids). The lower value of the range is based on inclusion of every OTC product line listed in the Nielsen data except toothpaste and sunscreens. The higher value excludes eye products, first aid, foot preparations, oral care, sun products, and undefined ''others.'' Note that the higher value will overstate the value of the cough and cold medication market because it includes some non-drug products, such as cough drops.

[4] Data available at *http://www.drugtopics.com*. Note that the data probably do not cover convenience stores and other nonconventional outlets. Even the lower estimate of the pseudoephedrine part of the market is overstated because it includes sales values for product lines that contain 4 to more than 20 products, only one of which contains pseudoephedrine.

[5] As discussed in DEA's October 19, 2006, ''Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2007: Proposed'' (71 FR 61801) and a subsequent notice establishing the assessment for 2007 (72 FR 53908, September 20, 2007), 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 Health Government Solutions, to develop the initial estimate of the medical needs of the United States of ephedrine and pseudoephedrine. IMS provided DEA with two reports: ''Methodology Used in Developing Preliminary Estimates of Ephedrine and Pseudoephedrine 2005 Legitimate Use'' (and ''2005 Ephedrine/Pseudoephedrine Legitimate Medical Use Methodology and Final Report'' (July 3, 2007). Both reports may be found at *http://www.deadiversion.usdoj.gov/meth/index.html*.

[6] Comment to ''Import and Production Quotas for Certain List I Chemicals'' (72 FR 37439, July 10, 2007) [Docket No. DEA–293, RIN 1117–AB08] available at *http://www.regulations.gov*.

TABLE 3.—COMMENTER'S IMPLIED VALUE OF THE PSEUDOEPHEDRINE (PSE) SALES AT CONVENIENCE STORES

Ephedrine/PSE	Implied PSE market (ephedrine market = $166m)	Implied PSE market (ephedrine market = $237m)
Ephedrine = 2% of PSE Sales	$8.3 billion	$11.85 billion.
Ephedrine = 6.60% of PSE Sales	$2.5 billion	$3.6 billion.
Ephedrine = 20% of PSE Sales	$830 million	$1.185 billion.

Because convenience store sales of these products represent only 3 percent of all sales, even using the lowest number the commenter provided (ephedrine sales of $166 million representing 20 percent of pseudoephedrine sales), the commenter's estimates produce an implied value of the total ephedrine and pseudoephedrine nonprescription market across all retail sectors of $33 billion, or between 4.5 and 7 times the actual retail market for all cough and cold medications and almost twice the size of the entire nonprescription drug retail market of $18 billion.

The commenter claimed that the ephedrine quota, which no importer or manufacturer objected to, would lead to job losses. Even the commenter's own overestimates indicate that job losses are highly improbable. If all ephedrine products were removed from the market at these outlets, which is unlikely, the daily sales loss would be very low even at the commenter's exaggerated levels. At more realistic market values, the daily losses would be trivial. Table 4 presents the average value of daily sales using the commenter's estimates of the value of ephedrine sales ($166 million to $237 million) and the number of convenience stores selling the products based on the commenter's estimate (72,500), Census data (41,000), and DEA data (28,000). The table also presents the more reasonable level of daily sales based on an estimate of the value of ephedrine sales at nonconventional outlets ($24 to $36 million). The more reasonable estimates may still be overestimates because they are based on a series of conservative assumptions: That nonconventional outlets sell 3 percent of nonprescription drugs or $532 million (Census data), that cough and cold medications represent 27 to 40 percent of those sales (Consumer Healthcare Products Association and A.C. Nielsen data) or $142 million to $215 million, and that ephedrine products represent 20 percent of those sales (commenter's implied estimate assuming that only ephedrine and pseudoephedrine products are sold in this category) or $24 million to $36 million.

TABLE 4.—ESTIMATED DAILY SALES OF EPHEDRINE-CONTAINING PRODUCTS AT CONVENIENCE STORES

Source of No. of outlet estimate	Estimate No. of outlets	Estimated total value of ephedrine nonconventional outlet market	Daily sales of ephedrine products
Commenter	72,500	$166–$237 million ephedrine	$6.27–$8.96
Census	41,000		11.09–15.84
DEA Estimate	[7] 28,000		16.24–23.19
Commenter	72,500	24–36 million ephedrine	0.89–1.36
Census	41,000		1.58–2.40
DEA Estimate	28,000		2.32–3.51

It is not reasonable to think that this level of sales loss, which represents considerably less than the cost of a single car buying a tank of gasoline, would affect employment as the commenter claimed. With about 28,000 convenience stores continuing to sell these products, there is no reason to think that all or even most such sales will be lost. As DEA stated in its Interim Final Rule implementing the procedures for import and production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine (72 FR 37439, July 10, 2007), its concern is with a limited number of high dosage unit products that are sold almost exclusively through nonconventional outlets and the Internet, not with low dosage unit products that are sold through both conventional and nonconventional outlets.

The commenter's claim that eliminating sales of ephedrine products at convenience stores, which neither DEA's Interim Final Rule establishing the procedures for implementation of quotas for ephedrine, pseudoephedrine, or phenylpropanolamine, nor this notice would do, would harm the public is also not supported. The IMS Health Government Solutions study that DEA used to adjust the Assessment of Annual Needs for 2007 indicated that ephedrine sales at convenience stores had dropped after states implemented controls on sales, but that sales at conventional stores increased; total sales of ephedrine products actually grew. Although this change may produce minor harm to convenience stores, or serious harm to the commenter, as it claimed, economically it is a transfer. Other stores and distributors have benefited by the shift, and the economy as a whole has not been affected. DEA notes that most stores in both categories—conventional and nonconventional outlets—are small businesses.

The commenter asserted that DEA had failed to consider the impact on small businesses. The only small entities directly affected by the Assessment of Annual Needs are manufacturers and importers, none of whom filed comments or objections to the assessment. The increased sales of ephedrine products shown in the IMS Health Government Solutions data indicate that these entities have not been harmed. The indirect effects of the assessment on downstream users, such as the commenter and its customers, are not subject to review under the

[7] The Combat Methamphetamine Epidemic Act of 2005 states that it is unlawful for any person who is a regulated seller to knowingly or recklessly sell at retail scheduled listed chemical products in violation of the requirements of 21 U.S.C. 830(e), including the requirement that regulated sellers self-certify to the Attorney General regarding compliance with the provisions of the Act (21 U.S.C. 842(a)(13)). As of October 12, 2007, 18,044 convenience stores had self-certified; DEA has identified another 10,000 that are selling the products.

Regulatory Flexibility Act or Executive Order 12866. In any case, as noted above, the data collected indicate that if some small entities have lost sales, others have gained sales, which is in economics terms a transfer. The total sales of ephedrine products appears to have increased (in terms of quantity, not value), which is why DEA adjusted the ephedrine assessment upward when establishing the assessment for ephedrine for 2007 (72 FR 53908, September 20, 2007). If the manufacturers and importers provide data that indicates that the ephedrine market is continuing to grow, DEA will adjust future assessments to meet the medical, scientific, research, industrial, and other legitimate needs of the United States.

In conclusion, the commenter has overestimated the size of the market for ephedrine products at convenience stores by a factor of at least six to ten, has made exaggerated claims about the impact on jobs when the daily sales values even using the commenter's overestimated claims are low, and has claimed damage to the economy when the data indicate that increased sales of the products at conventional outlets have more than offset sales losses at nonconventional outlets. Whatever effect the statutorily mandated restrictions have had on the commenter or nonconventional outlets, the cough and cold medication market continues to grow; there is no evidence to support the commenter's claim of a cost to the United States economy.

Use of the IMS Health Government Solutions Report

The commenter refers to the IMS Health Government Solutions study referenced above on numerous occasions throughout its comment. As discussed in DEA's October 19, 2006, proposed 2007 Assessment of Annual Needs Notice (71 FR 61801) and its September 20, 2007, established 2007 Assessment of Annual Needs Notice (72 FR 53908), DEA obtained assistance from a private independent contractor, IMS Health Government Solutions, to develop the initial estimate of the medical needs of the United States for both ephedrine and pseudoephedrine. The results from IMS' initial study were utilized by DEA to propose the 2007 Assessment of Annual Needs. The commenter claimed that the IMS report underestimated legitimate demand for ephedrine sold in OTC drugs for respiratory ailments via convenience stores. The commenter further claimed that the study did not adequately address sales of ephedrine-based OTC drug products through the convenience store channel of distribution. The commenter claimed that since DEA relied on underestimated values of the medical need (as provided by IMS) when it established the 2007 Assessment of Annual Needs, these same values, as proposed for the 2008 assessment, would lead to inadequate supplies of drug products containing ephedrine and pseudoephedrine.

DEA Response: The commenter's belief that the IMS Health Government Solutions report underestimated the medical needs of ephedrine and pseudoephedrine OTC drug products is flawed in the same way that its belief regarding the economic impact of this notice is flawed, as discussed above. The commenter's conclusion about the IMS Health Government Solutions report is predicated on the assumption that the commenter's sales are representative of the industry as a whole. As explained below, this conclusion is not supported by applications that the DEA has received for individual import, manufacturing, and procurement quotas from DEA-registered importers and manufacturers for 2008.

DEA's Proposed 2008 Assessment of Annual Needs for Ephedrine (For Sale) and Pseudoephedrine (For Sale)

The comment received from the commenter is virtually identical to that submitted to the proposed 2007 Assessment of Annual Needs on October 19, 2006 (71 FR 61801). Then, as now, the commenter asserted that the IMS Health Government Solutions report underestimated the legitimate demand for ephedrine sold in OTC drug products. The commenter further asserted that DEA's Assessment of Annual Needs significantly understated the amount of ephedrine and pseudoephedrine required to satisfy legitimate medical, scientific, research, and industrial purposes and lawful imports. The commenter also claimed that the IMS Health Government Solutions study did not adequately address sales of ephedrine-based OTC drug products through the convenience store channel of distribution. The new information submitted by the commenter in this area is a two-page letter prepared by the statistician who had initially submitted a report to the commenter as part of the commenter's comments to the 2006 proposed assessments. In that letter, the statistician stated that the DEA's proposed medical use estimate (which is a component of the ephedrine (for sale) assessment, which also includes lawful export and inventory requirements) of 11,500 kg for ephedrine ''falls far short of the 130% to 900% range of increases that would be needed to put the earlier proposed quota in line with actual over-the-counter sales of ephedrine products.'' DEA notes the commenter did not provide any quantitative or qualitative data to support its belief that the DEA's Assessment of Annual Needs for pseudoephedrine (for sale) was too low.

DEA Response: The estimated ephedrine (for sale) requirements submitted by the commenter are not supported by the applications received by the DEA pursuant to 21 CFR part 1315. On July 10, 2007, DEA published an Interim Final Rule which established procedures for administering individual quotas to DEA-registered manufacturers and importers of controlled substances (72 FR 37439). Although the rule became effective immediately upon publication, DEA chose not to issue individual import, manufacturing, and procurement quotas to DEA-registered importers and manufacturers of these chemicals in 2007 after finalizing the 2007 Assessment of Annual Needs. DEA concluded that such action would negatively impact the immediate availability of these chemicals and the products derived therefrom. Instead, DEA stated on its web site (*http://www.deadiversion.usdoj.gov/meth/q_a.htm*) that it would solicit applications for individual 2008 quotas from DEA-registered manufacturers and importers with the intent of processing completed applications on or before January 1, 2008.

On July 12, 2007, DEA notified all 1,054 DEA registered manufacturers and importers of both controlled substances and List I chemicals in writing of the publication of the Interim Final Rule and its potential impact on companies' ability to import or manufacture the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, and products containing those chemicals after January 1, 2008. Those that received the letter would have included companies that manufacture ephedrine products for the convenience store market. Specifically, DEA advised each company to submit an individual application(s) for 2008 quota; DEA advised that if no application was received, then DEA would assess each company's importing and manufacturing requirements for 2008 to be zero and, consequently, no quota would be issued. However, applications for quota could be submitted during the 2008 calendar year.

In the first month and a half, prior to proposing the 2008 Assessment of Annual Needs (72 FR 53911, September

20, 2007), DEA received very few 2008 quota applications. Since that time, however, DEA has received significantly more quota applications from DEA registrants. In connection with each application, DEA has been contacting each applicant and gathering additional information necessary to process each of these individual quota applications by the January 1, 2008 deadline. DEA has analyzed the statistical data provided by these registrants and the results of this analysis (below) are not consistent with the commenter's comments.

Analysis of Quota Applications for Ephedrine (For Sale)

Based on an analysis of the inventory, acquisition (purchases) and disposition (sales) data provided by DEA-registered importers and manufacturers of ephedrine products on individual quota applications received since publication of the July 10, 2007 Interim Final Rule, manufacturers of dosage form products containing ephedrine reported sales totaling approximately 3,900 kg in 2007; this represents a 61 percent decrease from sales reported by these firms for 2005 and a 49 percent decrease from the sales reported for 2006, as shown on the same quota applications. During the same period, exports of ephedrine products from the United States, as reported on export declarations (DEA Forms 486) received, are expected to total 245 kg in 2007, a 90 percent decrease from levels observed in 2005. These sales and export trends, when taken along with necessary inventory allowances, may suggest that DEA's 2008 Assessment of Annual Needs for ephedrine, as proposed, is too high, and may require and adjustment downward in the future.

Analysis of Quota Applications for Pseudoephedrine (For Sale)

Based on an analysis of the inventory, acquisition, and disposition data provided by DEA-registered importers and manufacturers of pseudoephedrine products on individual quota applications received since publication of the July 10, 2007 Interim Final Rule, manufacturers of dosage form products containing pseudoephedrine reported sales of these products totaling approximately 277.8 metric tons (MT; 1000 kg equals 1 MT) in 2007; this represents a 38 percent increase from sales data provided by these firms for 2005 and a 2 percent increase from sales reported in 2006, as shown on the same quota applications. During the same period, exports of pseudoephedrine products from the United States, as reported on export declarations (DEA Forms 486) received, are expected to total 29,145 kg in 2007, a 67.6 percent decrease from levels observed in 2005. These sales and export trends, when taken along with necessary inventory allowances, may suggest that DEA's 2008 Assessment of Annual Needs for pseudoephedrine, as proposed, is too high, and may require an adjustment downward in the future.

Although the analysis of quota applications received by DEA would support a decrease in the Assessment of Annual Needs for both ephedrine (for sale) and pseudoephedrine (for sale), DEA cannot ensure that it has applications from all those who may require an individual quota in 2008. Specifically, manufacturers and importers may have purchased increased amounts of these List I chemicals during the 2007 calendar year in anticipation of the establishment of individual quotas for the 2008 calendar year, thereby increasing their inventory position (i.e. stockpiling). As a result, these same DEA registrants may have elected to defer submission of individual quota applications until such time that these inventory levels decrease. Additionally, it remains unclear as to what impact, if any, phenylephrine will have on the market for cough and cold remedies containing pseudoephedrine. Finally, the Food and Drug Administration announced an enforcement action against unapproved drug products containing timed-release guafenesin in combination with other drugs, including ephedrine and pseudoephedrine (72 FR 29517, May 29, 2007). The Notice advises firms which are marketing unapproved products to obtain such drug approvals. As a result of this Notice, DEA believes that it may receive requests for quotas to support FDA validation requirements, thereby increasing the demand for ephedrine and/or pseudoephedrine for research purposes. For these reasons, DEA believes that the needs of the United States are best served by establishing the values initially proposed and therefore concludes the proposed amounts are sufficient to meet the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. DEA will propose a revision to, and subsequently finalize, the Assessment of Annual Needs for 2008 during the calendar year, thereby giving interested persons an opportunity to provide substantive data to support or refute any proposed changes to assessments.

Comment Period

The commenter believed that DEA's comment period of 21 days (September 20, 2007, to October 11, 2007,) was too short, making it impossible, the commenter claimed, for affected parties to provide significant comment within a short window of opportunity. The commenter requested that DEA reopen the comment period for an additional sixty days.

DEA Response: When DEA published its July 10, 2007, Interim Final Rule establishing procedures for administering the assessment of annual needs and individual import, manufacturing, and procurement quotas, DEA stated that it had ''good cause'' under the Administrative Procedure Act to implement those regulations without engaging in traditional notice and comment rulemaking. In support of that action, DEA specifically stated:

> Congress, in crafting CMEA, recognized that limiting of product availability at the retail level could potentially encourage diversion of either drug products or the List I chemicals themselves higher in the supply chain—at the import, manufacture, and distribution levels. To address its concern about ''what immediately moves in behind,'' (Rep. Souder, February 28, 2006, CR p. 423) Congress included provisions in CMEA to control the import, export, manufacture, and distribution of the three chemicals and products containing them. These provisions also will make it possible for the United States to meet the recommendations of the International Narcotics Control Board, which encouraged its member countries to provide for pre-export notifications and an assessment of legitimate need for these chemicals. * * *
>
> DEA must implement the quota provisions of the CMEA on an interim basis to ensure that product upstream from the retail level is not diverted for illicit purposes. It would be contrary to the public interest to allow the diversion of large amounts of ephedrine, pseudoephedrine, and phenylpropanolamine at the wholesale level while implementing controls at the retail level to limit sales of these very products.
>
> The broad scope of the new law [CMEA], as well as the expedited effective dates, is a clear reflection of Congress' concerns about the nation's growing methamphetamine epidemic and its [Congress] desire to act quickly to prevent further illicit use of these chemicals.'' (specifically 72 FR 37443–37444)

DEA's decision to provide a 21-day comment period was based on Congress' mandate for DEA to act quickly to implement the requirements of the CMEA including the establishment of an Annual Assessment of Needs and individual import, manufacturing, and procurement quotas. The regulations require that DEA establish the Assessment of Annual Needs prior to the issuance of individual quotas, meaning that DEA must establish the 2008 Assessment of Annual Needs before it can issue individual import,

manufacturing, and procurement quotas. DEA is required to complete the process of issuing individual import, manufacturing, and procurement quotas prior to January 1, 2008, as quotas are issued for a calendar year. DEA believes that a shorter comment period was necessary to review and consider the comments received from the public and then establish the 2008 Assessment of Annual Needs prior to the end of the 2007 calendar year.

DEA also believes that a 21-day comment period was sufficient given that its proposal was neither complex nor technical. DEA notes that two of the 2008 assessments proposed were values initially proposed on October 19, 2006, when DEA proposed the 2007 Assessment of Annual Needs, and the other three values were values significantly higher than the values proposed on October 19, 2006. Additionally, DEA notes that interested persons directly impacted by these quotas (i.e., DEA-registered manufacturers and importers) learned of the factors DEA would consider in the establishment of individual quotas in July when the Interim Final Rule was published. Many of these factors are set forth by statute; any remaining factors parallel the current system which has existed for individual quotas for controlled substances essentially since the inception of the Controlled Substances Act. For these reasons, DEA believes that DEA registrants had ample time to gather the necessary scientific and technical information that would be required to submit substantive comments to the proposed 2008 Assessment of Annual Needs.

Finally, DEA believes that the commenter did not proffer any specific information beyond that which it submitted in its written comments that would be brought to light if the DEA were to extend the comment period.

Withdrawal of 2008 Proposed Assessment of Annual Needs

The commenter requested that the proposed 2008 Assessment of Annual Needs be withdrawn and reproposed, presumably based on its comments.

DEA Response: After considering the commenter's comments, the DEA has determined that the request for a withdrawal of the proposed 2008 Assessment of Annual Needs is unnecessary for the reasons discussed above.

Conclusion

DEA has carefully considered the comment received from the lone commenter in connection with the proposed 2008 Assessment of Annual Needs. Based on information provided in the comment, along with information provided by DEA-registered manufacturers and importers of these List I chemicals on applications for individual import, manufacturing, and procurement quotas pursuant to DEA regulations, DEA has fully addressed the relevant issues set forth in the comment. 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 2008 Assessment of Annual Needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, be established as follows:

List I Chemical	Established 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

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 not have a significant economic impact upon a substantial number of small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601–612. The establishment of Assessment 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 lawful 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: December 18, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 21, 2007, and published in the **Federal Register** on September 27, 2007, (72 FR 54929–54930), Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedules I and II:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Dihydromorphine (9145)	I
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Sufentanil (9740)	II
Fentanyl (9801)	II
Remifentanil (9739)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.