DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–300P]


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 such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 2 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.

[FR Doc. E6–17525 Filed 10–18–06; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Notice 71 FR 39876, August 5, 2006; 300P]


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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: 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

<table>
<thead>
<tr>
<th>List I chemicals</th>
<th>2005 export quantity (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine</td>
<td>2,540</td>
</tr>
<tr>
<td>Pseudoephedrine</td>
<td>90,260</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>List I chemicals</th>
<th>Proposed year 2007 quotas (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine (for sale)</td>
<td>7,100 kg</td>
</tr>
<tr>
<td>Ephedrine (for conversion)</td>
<td>126,760 kg</td>
</tr>
<tr>
<td>Pseudoephedrine (for sale)</td>
<td>511,100 kg</td>
</tr>
<tr>
<td>Phenylpropanolamine (for conversion)</td>
<td>5,545 kg</td>
</tr>
</tbody>
</table>

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.


Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E6–17526 Filed 10–18–06; 8:45 am]

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, dihydromorphone, diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydrocodone, hydromorphone, oxymorphone, methadone, methylphenidate, morphone (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, hydromorphone, oxymorphone, and thebaine to meet the legitimate needs of the United States.

Regarding amphetamine, dihydrocodeine, diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydromorphone, 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: