

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The commenter requested that the proposed 2008 Assessment of Annual Needs be withdrawn and repropose, presumably based on its comments.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

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cedarburg Pharmaceuticals, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cedarburg Pharmaceuticals, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 16, 2007, and published in the **Federal Register** on August 27, 2007, (72 FR 49020), Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, 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
4-Methoxyamphetamine (7411).	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724) ..	II
Pentobarbital (2270)	II
Codeine (9050)	II
Dihydrocodeine (9120) ...	II
Oxycodone (9143)	II
Hydromorphone (9150) ...	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II

Drug	Schedule
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

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

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Chattem Chemicals, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Chattem Chemicals, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

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

[FR Doc. E7-25040 Filed 12-26-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated August 28, 2007 and published in the **Federal Register** on September 10, 2007, (72 FR 51664), CIMA Labs, Inc., 7325 Aspen Lane, Brooklyn Park, Minnesota 55428 made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of Nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to import the basic class of controlled substance for clinical trials and research.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of CIMA Labs, Inc. to import the basic class of controlled substance is

consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated CIMA Labs, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: December 18, 2007.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 16, 2007, and published in the **FEDERAL REGISTER** on August 27, 2007, (72 FR 49021), Cody Laboratories, 601 Yellowstone Avenue, Cody, Wyoming 82414, 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
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120) ...	II
Oxycodone (9143)	II
Hydromorphone (9150) ...	II
Diphenoxylate (9170)	II
Meperidine (9230)	II
Methadone (9250)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans on manufacturing the listed controlled substances in bulk for sale to its customers.