

comments from the public and affected agencies. Comments are encouraged and will be accepted until January 26, 2004. Written comments and suggestions are requested from the public and affected agencies concerning the proposed collections of information.

Comments should address one or more of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument(s) with instructions, if applicable, or additional information, please contact Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

Overview of *Report of Medical/First Aid Kit Provider Business Activities* Information Collection:

(1) *Type of information collection:* new collection.

(2) *The title of the form/collection:* Report of Medical/First Aid Kit Provider Business Activities.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form No.: None.

Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.
Other: None.

Abstract: The collection of this information is necessary to maintain appropriate oversight of the distribution

of regulated drug products containing List I chemicals by requiring notification from businesses of their intent to distribute retail subthreshold quantities of pseudoephedrine drug products for the purpose of supplying/replenishing medical/first aid kits.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 600 Respondents. 600 responses per year \times 1 hour per response = 600 hrs.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 600 annual burden hours. 600 respondents \times 1 hour per respondent per year.

Overview of *Report of Distribution of Sample Packages* Information Collection:

(1) *Type of information collection:* new collection.

(2) *The title of the form/collection:* Report of Distribution of Sample Packages.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form No.: None.

Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.
Other: None.

Abstract: The collection of this information is necessary to maintain appropriate oversight of the distribution of regulated drug products containing retail below-threshold amounts of pseudoephedrine. By requiring notification from businesses of their intent to distribute sample packages containing not more than two solid dosage units, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, to the general public. Distributions are limited to not more than one package distributed to an individual or residential address in any 30-day time period. Notice provides the business name and address and acknowledges distribution restrictions, compliance with the requirements of Title 21, Code of Federal Regulations (CFR), part 1310, the reporting and recordkeeping requirements, and the fact that exemption from the registration requirement applies to this activity only.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to*

respond/reply: 1,000 respondents. 1,000 responses per year \times 1 hour per response = 1,000 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,000 annual burden hours. 1,000 respondents \times 1 hour per respondent per year.

If additional information is required regarding these collections of information, contact: Brenda E. Dyer, Deputy Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small business entities. These proposed regulations would ease registrants', primarily small businesses, regulatory burdens including waiving the requirement of registration and exempting certain regulated persons from the imposition of registration fees.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866, Section 1(b). DEA has determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget. Further, the proposed information collections, "Report of Medical/First Aid Kit Provider Business Activities" and "Report of Distributions of Sample Packages", have been submitted for review. This rulemaking eases the regulatory burden for registrants by waiving the requirement of registration for certain activities, as well as exempting certain regulated persons from the registration fees. Were DEA not to propose these regulations, thereby codifying present Administration policy, each affected person would be required to register with DEA annually and pay an initial registration fee of \$595 and annual reregistration fees of \$477. If finalized, these proposed regulations will require exempt persons to notify DEA only once of their activities, at a cost of mailing one letter, as opposed to an annual registration fee. Industry would benefit