

limited to, ephedrine, pseudoephedrine and phenylpropanolamine (used in the manufacture of pharmaceutical products), benzaldehyde (used in the manufacture of perfumes and dyes), hydriodic acid (a disinfectant and chemical reagent), nitroethane (a solvent), and white phosphorus (used in the production of other phosphoric compounds). As a rule, with the exception of pseudoephedrine, phenylpropanolamine, and ephedrine, which are distributed to the public in regulated form as over-the-counter medications, List I chemicals in regulated form are usually distributed in commercial transactions between businesses and only rarely to the public in retail transactions. It is within this commercial arena that contract processors operate; they do not distribute at retail to the public.

The proposed waiver of the requirement of registration or reregistration for distributors of research/reference standards would affect the List I chemicals ephedrine, pseudoephedrine and phenylpropanolamine. The proposed waiver of the requirement of registration or reregistration for medical/first aid kit providers and distributors of sample packages would affect the List I chemical pseudoephedrine. Pseudoephedrine, a chemical widely used in over-the-counter medications, is a decongestant used for the temporary relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies. Products containing pseudoephedrine are widely available in a variety of dosage forms as a single entity or in combination with antihistamines, antitussives, analgesics, expectorants, and/or vitamins. Ephedrine is used for the temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.

The majority of the products purchased by the public containing pseudoephedrine are commonly used medications and are easily accessible at pharmacies, grocery stores, discounted department stores, and a variety of other retail stores. These products are available to the public without a prescription. A few products containing pseudoephedrine or ephedrine are prescription products and require a prescription issued by a practitioner prior to being dispensed to a patient. This proposed regulation will not adversely impact the public's ability to easily access these products.

II. Waivers of the Requirement of Registration

A. Contract Processors

What Are Contract Processors?

Contract processors, sometimes referred to within the industry as "tollers", are those persons who, through a legally binding agreement with a registrant, take physical possession of a listed chemical for the purpose of providing a processing service to the registrant. Such processes may include, but are not limited to, packaging a product and adding chemicals to a mixture. The contract processor never has legal ownership or control of the chemicals; legal title remains with the registrant. Following processing, the contract processor either returns all of the chemicals received to the registrant, or distributes them as required by the registrant.

Why Is DEA Waiving the Requirement of Registration for Contract Processors?

In reviewing this situation, DEA has noted that activities of certain contract processors parallel those of a warehouse at which chemicals are stored, for which an exemption from registration has been provided under 21 U.S.C. 822(c) (21 CFR 1309.23(b)(1)). As with the warehouseman, the contract processor merely carries out the processing requirements of the registrant; the contract processor does not have, at any time, legal title to or legal control of the chemicals. The registrant provides the material to the contract processor for a specific function, after which the material is returned to the registrant, thus maintaining a closed-loop system. DEA has determined that, under such circumstances, the requirement of registration is not necessary for effective chemical control. Therefore, DEA is proposing to amend the regulations to waive the requirement of registration for contract processors provided that chemicals are distributed only back to the registrant. As with warehousemen, a registrant utilizing a contract processor's services would be responsible for exercising due care in selection of the processor (21 CFR 1309.71, 21 CFR 1309.72). The registrant would have to ensure that the contract processor has in place appropriate procedures and safeguards to protect chemicals from diversion.

What Circumstances Are Not Permitted Under This Waiver?

Contract processors do not always operate within a closed-loop system. In some cases, a contract processor may receive chemicals from an outside

source, process them, and distribute the chemicals to the registrant. In other cases, a registrant may provide the chemicals to the contract processor which processes them and, per the registrant's instructions, distributes the chemicals to other persons. These activities deviate from the closed-loop system between the registrant and contract processor and involve distributions to or from other registrants. Therefore, these types of activities will remain subject to the registration requirements under the law. DEA is proposing that, as with the existing provisions for warehouses, the waiver will apply only to those circumstances in which a registrant distributes directly to a contract processor which, in turn, will distribute only back to the registrant from which it received the chemicals.

B. Medical/First Aid Kit Providers

What Are Medical/First Aid Kit Providers?

Medical/first aid kit providers distribute small amounts of pseudoephedrine drug products, in individual transactions, to medical/first aid kits maintained by businesses for the personal medical use of employees in the workplace. The distributions are usually conducted in face-to-face transactions (an agent or employee of the distributor delivers the products directly to the customer), the products are distributed for the personal medical use of the employees of the customer, and are less than the retail threshold per transaction. [As used in this document and referenced in the Methamphetamine Anti-Proliferation Act of 2000 (Section XXXVI of Pub.L. 106-310), the term "transaction" is defined to mean the provision of regulated drug products to a specific location, *not* the provision of regulated drug products to a specific medical/first aid kit within a location. Thus, under the terms of this proposed waiver, if a location had multiple medical/first aid kits, the medical/first aid kit provider would be permitted to supply the location with a quantity of product below the retail per-transaction limit during each visit to that specific location. Product may be allocated to multiple medical/first aid kits throughout a specific location, without the medical/first aid kit provider being required to register with DEA, so long as the amount of product distributed does not exceed the retail per-transaction threshold.]