

Why is DEA Waiving the Requirement of Registration for Medical/First Aid Kit Providers?

Medical/first aid kit provider activities closely parallel those of retail distributors; sales involve retail below-threshold amounts of the products, are made in face-to-face transactions, and are intended for the personal medical use of the employees of the business. DEA has determined that, where a medical/first aid provider's activities are restricted to retail below-threshold, face-to-face transactions to supply/replenish medical or first aid kits maintained for the personal medical use of employees in the workplace, application of the registration requirement is not necessary for effective enforcement of the chemical control program. Instead, the providers must submit written notice to DEA certifying that their activities will be limited to distribution of retail below-threshold quantities of a drug product containing pseudoephedrine that is regulated pursuant to § 1300.02(b)(28)(i)(D) for purposes of supplying/replenishing medical or first aid kits maintained by businesses for the use of their employees. (A model of the notice to be used may be found in proposed 1309.24(i).) Notice must be provided on official company letterhead to the Drug Enforcement Administration, Chemical Control Section, Washington, D.C. 20537.

Those medical/first aid kit providers currently operating pursuant to Memoranda of Understanding (MOU) with DEA will be required to request a waiver of the requirement of registration once the Final Rule implementing these regulations is published in the **Federal Register**.

Although medical/first aid kit providers conduct individual transactions in retail below-threshold quantities, they may store large quantities of drug products containing list I chemicals that are regulated pursuant to § 1300.02(b)(28)(i)(D) at any one time. Because of this, the issue of theft or loss of these drug products is of concern to DEA. It is extremely important that persons supplying/replenishing medical or first aid kits maintained by businesses for the use of their employees take adequate and appropriate measures to ensure the security of these drug products in their possession (21 CFR 1309.71–1309.73). Persons receiving a waiver of the requirement of registration should pay special attention to the storage and security of the regulated drug products. Further, waiver of the registration requirement does not obviate the need for complete and accurate

recordkeeping and reporting to DEA (21 CFR 1310, 1313). The waiver of the requirement of registration may be revoked or suspended under the terms discussed in Section II.E. of this preamble and the proposed regulations.

#### *C. Distributors of Sample Packages of Drug Products*

What Are Sample Packages, and When May the Requirement of Registration Be Waived for Distributions of Sample Packages?

It is not unusual for manufacturers of drug products containing retail below-threshold amounts of pseudoephedrine that are regulated pursuant to § 1300.02(b)(28)(i)(D) to distribute free samples of their products directly to the public as part of marketing campaigns. The samples may be distributed through mass distributions in newspapers, magazines, or through the mail. A sample package contains not more than two solid dosage units of the product, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package. DEA has determined that application of the specific registration requirement is not necessary for effective enforcement of chemical controls, provided that the sampler does not distribute more than one sample package of a drug product containing retail below-threshold amounts of pseudoephedrine that is regulated pursuant to § 1300.02(b)(28)(i)(D) to an individual or residential address in any 30-day time period. Instead, DEA will require that the sampler must submit written notice to DEA certifying that their activities will be limited to individual distributions of sample packages containing not more than two solid dosage units of the product, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and that distributions will not exceed one per individual or residential address per 30-day time period. Notice must be provided on official company letterhead to the local field office of the Drug Enforcement Administration. Contact information for local DEA field offices may be obtained from the Drug Enforcement Administration Web site at <http://www.dea.gov>. Once notification has been received, the local field office will provide instruction on handling the product.

Those persons distributing sample packages currently operating pursuant to Memoranda of Understanding (MOU) with DEA will be required to request a waiver of the requirement of registration once the final rule implementing these

regulations is published in the **Federal Register**.

Although distributors of sample packages may distribute only one sample package to an individual or residential address in a 30-day time period, they may store very large quantities of regulated drug products. The issue of theft or loss of these drug products is of concern to DEA. It is extremely important that persons making distributions of these sample packages take adequate and appropriate measures to ensure the security of these drug products in their possession (21 CFR 1309.71–1309.73). Persons receiving a waiver of the requirement of registration should pay special attention to the storage and security of the sample packages. Further, waiver of the requirement of registration does not obviate the need for accurate recordkeeping and reporting to DEA (21 CFR 1310, 1313). The waiver of the requirement of registration may be revoked or suspended under the terms discussed in Section II.E. of this preamble and the proposed regulations.

#### *D. Distribution of Research/Reference Standards*

What Are Distributions of Research/Reference Standards, and When May the Requirement of Registration Be Waived for These Distributions?

DEA registered manufacturers of regulated drug products sometimes maintain separate locations at which ephedrine, pseudoephedrine, and phenylpropanolamine research/reference standards are manufactured and distributed to other locations operated by the registrant for use in manufacturing processes. DEA has determined that requiring registration for such distributions is not necessary for effective enforcement of the chemical control program provided that the distributions are less than five (5) grams per transaction, not to exceed fifty (50) grams cumulatively per calendar month, and are made solely between locations operated by the same regulated person. The small amounts of material involved and the closed system within which the material is distributed do not present significant potential for diversion. Further, because these samples are used for research purposes, the controls surrounding these chemicals, as well as their chain of custody, are very strict. These added safeguards lessen the potential for diversion. Therefore, DEA is proposing the amendment of 21 CFR 1309.24 to waive the requirement of registration for the distribution of research/reference standards. The waiver of the