

chemicals that are regulated pursuant to 21 CFR 1300.02(b)(28).)

(d) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) of this chapter.

(e) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are limited to the distribution of below-threshold quantities of pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) of this chapter, in a single transaction to an individual for legitimate medical use, irrespective of whether the form of packaging of the product meets the definition of "ordinary over-the-counter pseudoephedrine or phenylpropanolamine product" under 21 CFR 1300.02(b)(31) of this chapter.

(f) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(g) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(h) The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

(i) The requirement of registration under this part is waived for any medical/first aid kit provider whose activities consist of distributing, in face-to-face transactions, a drug product containing retail below-threshold amounts of pseudoephedrine that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) to businesses for the sole purpose of supplying/replenishing a medical/first aid kit maintained for the personal use of employees in the workplace. For purposes of this paragraph, 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.

(1) Persons requesting a waiver of the requirement of registration must submit a notification of this business activity on official company letterhead to the Drug Enforcement Administration, Office of Diversion Control, Chemical Control Section, Washington, DC 20537.

(2) Notification of this business activity should be in the following form:

I, _____ the _____ (title) of _____ (name of company) located at _____ (street address) _____ (city) _____ (state) _____ (ZIP code) am writing to request a waiver of the Drug Enforcement Administration (DEA) chemical registration requirement for _____ (name of company)'s activities involving the distribution of drug products containing pseudoephedrine that are regulated pursuant to Title 21, Code of Federal Regulations, § 1300.02(b)(28)(i)(D) to businesses for the purpose of supplying/replenishing medical or first aid kits maintained by those businesses for the personal medical use of their employees.

This is to certify that _____ (name of company) will comply with the provisions of Title 21, Code of Federal Regulations, Part 1309, namely:

1. The distribution of retail below-threshold amounts of drug products containing pseudoephedrine that are regulated pursuant to § 1300.02(b)(28)(i)(D) are to individual customers;

2. The distributions are made only in face-to-face transactions; and

3. The distributions are only for the purpose of supplying/replenishing medical or first aid kits maintained by businesses for the personal medical use of their employees.

_____ (name of company) distributes an average of _____ dosage units of pseudoephedrine products per year.

I understand that the waiver of the registration requirement applies only to those activities; any distribution of the products other than as described above is subject to the registration requirement.

Further, I understand that the waiver applies only to the registration requirement. The recordkeeping and reporting requirements set forth in Title 21, Code of Federal Regulations, Part 1310, still apply to both receipts and distributions of products containing a List I chemical that are regulated pursuant to Title 21, Code of Federal Regulations, § 1300.02(b)(28)(i)(D). I understand that if I receive more than a non-retail threshold amount of pseudoephedrine, either singly or cumulatively, in a calendar month from a supplier, then I must keep a record of such receipt(s).

I understand that I will receive a written decision regarding my request for a waiver of the requirement of registration. I further understand that to engage in the distribution of drug products containing pseudoephedrine that are regulated pursuant to Title 21, Code of Federal Regulations, § 1300.02(b)(28)(i)(D) to medical/first aid kits

I must either be registered with the Drug Enforcement Administration as a List I chemical handler or have received a written waiver of the requirement of registration. A copy of this letter will be kept in my records.

(signature)

(title)

(date)

(3) The request for a waiver of the requirement of registration will be evaluated based on compliance with the above criteria and on public interest criteria as defined in 21 U.S.C. 823(h). Once a determination has been made regarding the request for waiver, DEA will notify the requestor in writing of the decision.

(4) Public reporting burden for collection of this information is estimated to average 1 hour per response, including the time to review instructions, write the request, and send it to the appropriate location. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-00xx, Washington, DC 20503.

(j) The requirement of registration under this part is waived for persons distributing sample packages of a product containing retail below-threshold amounts of pseudoephedrine that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) 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. Distributions are limited to not more than one package distributed to an individual or residential address in any 30-day period.

(1) Persons requesting a waiver of the requirement of registration must submit a notification of this business activity on official company letterhead to the Special Agent in Charge of the Administration in the area in which the person is located.

(2) The Special Agent in Charge shall authorize and instruct the person distributing the sample packages on handling and security of the product.

(3) Public reporting burden for collection of this information is estimated to average 1 hour per response, including the time to review instructions, write the notification, and send it to the appropriate location. Send comments regarding this burden