Corrections

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This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309, 1310

[Docket No. DEA–239T]

Clarification of the Exemption of Sales by Retail Distributors of Pseudoephedrine and Phenylpropanolamine Products

Correction

In rule document 04–722 beginning on page 2062 in the issue of Wednesday, January 14, 2004, make the following correction:

On page 2065, the table is corrected to read as follows:

Qualifications and Requirements for the Exemption of Sales of ''Ordinary Over-the-Counter Pseudoephedrine or Phenylpropanolamine Regulated Products'' (''Safe Harbor Products'') by Retail Distributors

Seller must first meet the definition of retail distributor relating to regulated pseudoephedrine, phenylpropanolamine, or ephedrine products listed below:

1. Means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine or phenylpropanolamine are—

2. Limited to sales almost exclusively for personal use, both in the number of sales and volume of sales [regardless of the packaging of the products].

Sale for personal use means the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.

AND

3. Sales are made either directly to walk-in customers or face-to-face by direct sales. (21 U.S.C. 802(46) & 21 CFR 1300.02(b)(29))

Requirements and conditions if retail distributor qualifies for the exemption	Requirements and conditions if retail distributor does not qualify for the exemption
DEA registration as a distributor of List I chemicals is waived. (21 CFR 1309.23(e)).	Seller must register with DEA as a distributor of List I chemicals. (21 CFR 1309)
As a regulated person whose registration has been waived, a retail distributor must meet security requirements for List I chemicals found in 1309.71–1309.73. (21 CFR 1309.24(k)).	Distributor must meet security requirements for List I chemicals in 21 CFR 1309.71–1309.73.
As a regulated person whose registration has been waived, a retail distributor is subject to the to the reporting requirements for regulated transactions requirements of listed chemicals in 21 CFR 1310.05. (21 CFR 1309.24(k)).	Distributor is subject to the reporting requirements for listed chemicals in 21 CFR 1310.
No records are required for sales of regulated pseudoephedrine or phenylpropanolamine products below threshold quantities in a single transaction regardless of packaging (not a regulated transaction).	No records are required for sales of regulated pseudoephedrine or phenylpropanolamine products below threshold quantities in a single transaction regardless of packaging (not a regulated transaction).
Records must be retained for all sales of threshold and above quantities of pseudoephedrine and phenylpropanolamine regulated products not in blister packs (such as bottles), which are regulated transactions, as set forth in 21 CFR 1310.	Records must be retained for all transactions of threshold or above quantities regardless of type of packaging (regulated transactions). (21 CFR 1310)
If sales of pseudoephedrine or phenylpropanolamine regulated products exceed ''almost exclusively below-threshold'' amounts either in number of sales or volume of sales—regardless of the kind of packaging, then seller must register with DEA as a distributor of List I chemicals. (See the other side of this table—Requirements and Conditions If Retail Distributor Does Not Qualify for the Exemption.).	For all transactions at or above threshold amounts (regulated transactions), distributor must meet proof of identity requirements for customers. (21 CFR 1310.07)

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