

the definition of "ordinary over-the-counter pseudoephedrine or phenylpropanolamine product" (see 21 U.S.C. 802(45)) are subject to the threshold requirements of MAPA. This includes the single transaction threshold of 9 grams as base and the single package size of 3 grams or less of pseudoephedrine or 3 grams or less of phenylpropanolamine as base. The requirement of registration is waived for retail distributors whose activities consist solely of below-threshold distributions to an individual for a legitimate medical purpose (21 CFR 1309.24(e)). Retail distributors who engage in single transactions at or above 9 grams of pseudoephedrine or phenylpropanolamine as base or single transactions of package sizes containing more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base per package will void their waiver of the registration requirement and must register with DEA. Transactions above these thresholds are regulated transactions and subject to all requirements of the Controlled Substances Act. For retail transactions, this would include customer identification, recordkeeping, and reporting.

For those required to submit mail order reports, the 9 gram transaction threshold (as base) for a single transaction and the 3 gram package size (as base) apply to every transaction involving pseudoephedrine, phenylpropanolamine or drug products containing them—regardless of the type of packaging for the products. There are no exemptions for ordinary over-the-counter pseudoephedrine and phenylpropanolamine products. All of the requirements of the CSA apply to

threshold and above transactions and to above-threshold package sizes, that is, registration, identification, recordkeeping, and reporting, as well as the monthly mail order reports submitted to DEA.

What Are the Changes to the Mail Order Reporting Requirement?

MAPA provides the following exemptions to the mail order reporting requirement: Transactions involving sample packages of drug products, deliveries of prescriptions to consumers by retail distributors, distributions to long-term care facilities and their residents, mail order prescription deliveries, and exports already reported to DEA on a Form 486 or granted a waiver by the Administrator. These were specifically cited in the section of this rulemaking titled, "Why is DEA publishing a final rule?"

Congress also granted the Attorney General the authority (delegated to the Administrator of DEA) to develop regulations to expand the Congressional list of exemptions.

What Action Is DEA Taking To Codify the MAPA Amendments in Its Regulations?

To implement the requirements of MAPA, DEA is adding the new definitions of "drug product" and "valid prescription" at 21 CFR 1300.02, and updating §§ 1310.03 and 1310.05 to reflect the revised reporting requirements for mail order distributions. Specifically, DEA is amending § 1310.05 to explicitly exempt from the reporting requirements the low-risk categories of mail order transactions previously listed.

DEA also reserves the right to exempt, by regulation, from the reporting

requirements any other quantity, method, or type of distribution of a specific listed chemical (or drug product containing it) or group of listed chemicals (or drug products containing them) determined by the Administrator to be unnecessary for the effective enforcement of the Controlled Substances Act.

What Is the Effect of MAPA on the Public and on Industry?

MAPA will not adversely impact the public's access to pseudoephedrine and phenylpropanolamine products. The majority of the products purchased by the public are commonly used medications most of which are available without a prescription at pharmacies, grocery stores, discount department stores, and a variety of other retail stores. Although the thresholds are being reduced, these thresholds still permit the public adequate access to these drug products for legitimate medical purposes, which include their use as decongestants for the temporary relief of nasal congestion. Each of the products is available as a single entity or in combination with antihistamines, antitussives, analgesics, and expectorants. Sale of a single package of drug product containing 3 grams or less per package of pseudoephedrine or phenylpropanolamine base is not a regulated transaction. A single transaction of less than 9 grams of pseudoephedrine or phenylpropanolamine as base is not a regulated transaction. The chart below indicates the number of tablets per package and per single transaction that constitute a regulated transaction. One tablet less would be a non-regulated transaction.

NUMBER OF TABLETS THAT CONSTITUTE A REGULATED TRANSACTION FOR DOSAGE UNITS OF MARKETING PRODUCTS *

| Product type | Number of tablets over 3-gram package size | Number of tablets per 9-gram transaction |
|-----------------------------|--|--|
| Pseudoephedrine | | |
| 120-mg Hydrochloride | 31 | 92 |
| 120-mg Sulfate | 33 | 98 |
| 60-mg Hydrochloride | 62 | 184 |
| 60-mg Sulfate | 65 | 195 |
| 30-mg Hydrochloride | 123 | 367 |
| 30-mg Sulfate | 130 | 390 |
| Phenylpropanolamine | | |
| 75-mg Hydrochloride | 50 | 149 |
| 25-mg Hydrochloride | 149 | 447 |
| 12.5-mg Hydrochloride | 298 | 894 |
| 6.25-mg Hydrochloride | 596 | 1,788 |

* Calculated as base.