

For example, if a member of the public purchased product containing 30-mg pseudoephedrine hydrochloride tablets in a single transaction of 366 tablets, it would not be regulated. However, if that person purchased 367 or more tablets of the same product in a single transaction, it would be a regulated transaction. The member of the public would still be permitted to make such a purchase, but would be required to provide the distributor with certain information. DEA believes that few members of the public make such large purchases for legitimate personal medical use, and thus will not be adversely impacted by this rulemaking.

Due to concerns regarding possible harmful side effects, the Food and Drug Administration initiated action in November 2000 to remove phenylpropanolamine from the market. As a result, many firms voluntarily discontinued marketing products containing it. Because MAPA specifically addresses phenylpropanolamine and there remain legitimate veterinary uses for it that will ensure some level of its continued production and availability, this action continues to apply to phenylpropanolamine.

MAPA will affect persons who sell drug products containing pseudoephedrine or phenylpropanolamine to the public. This includes retail distributors and persons required to submit mail order reports. For retail distributors, single transactions containing 9 grams or more of pseudoephedrine or phenylpropanolamine as base are regulated transactions. Single transactions in which a package contains more than 3 grams of pseudoephedrine base or more than 3 grams of phenylpropanolamine base are also regulated transactions. Above-threshold transactions will still be permitted, but will be subject to all the requirements of a regulated transaction, including registration of the distributor—as selling over-threshold amounts of these products voids the retail distributor exemption (21 CFR 1309.24(e)), identification of customers (21 CFR 1310.07), maintenance of records (21 CFR 1310.04), and the filing of reports with the Administration (21 CFR 1310.05, 1310.06). It is important to note, however, that many retail distributors have already voluntarily limited their sales in a single transaction to amounts equal to or less than those finalized in this rulemaking to help prevent diversion of these products for the illicit manufacture of methamphetamine and amphetamine.

For those required to submit mail order reports, both the 9 gram transaction threshold and the 3 gram package size for pseudoephedrine and phenylpropanolamine drug products apply to every transaction—regardless of whether the transaction is one that must be reported. Single transactions of 9 grams or more of pseudoephedrine or phenylpropanolamine as base are regulated transactions and single transactions of package sizes containing more than 3 grams of pseudoephedrine or phenylpropanolamine as base are regulated transactions. Regulated transactions subject the distributor to the following requirements—identification of the customer (21 CFR 1310.07), recordkeeping (21 CFR 1310.04), and reporting (21 CFR 1310.05 and 1310.06), in addition to the requirement to submit monthly reports of all transactions (21 U.S.C. 830(b)(3)).

MAPA added language requiring monthly mail order reports for export transactions with nonregulated persons involving ephedrine, pseudoephedrine, phenylpropanolamine, and drug products containing them which use or attempt to use the Postal Service, or any private or commercial carrier. Every export transaction for these chemicals and for drug products containing them must be reported on a monthly basis unless the export transaction is exempt. Exempt export transactions include those reported on a DEA Form 486 and those for which the Administrator has waived monthly reporting.

To reduce the burden on those who are subject to the monthly mail order reporting requirement under 21 U.S.C. 830(b)(3), MAPA added exemptions to this requirement. These exemptions include distributions of samples of drug products, deliveries of prescriptions to consumers by retail distributors, distributions of drug products to long term care facilities and their residents, mail order prescription deliveries, exports reported to DEA on a Form 486, and any quantity, method, or type of distribution of a specific listed chemical or group of listed chemicals which the Attorney General has excluded by regulation from this reporting requirement. These exemptions were previously cited in the section of this rulemaking titled, “Why is DEA publishing a final rule?” The Administrator of DEA, through the delegation of authority from the Attorney General, may exclude by regulation from the mail order reporting requirement any quantity, method, or type of distribution of listed chemicals (including specific formulations or drug products) for which such reporting is considered not necessary for the

enforcement of law. DEA will consider any suggestions submitted regarding additional exemptions to the reporting requirement under 21 U.S.C. 830(b)(3) that may be warranted.

Technical Amendment

The final regulations implementing the provisions of the Comprehensive Methamphetamine Control Act (MCA) amended the waiver of the retail registration activity found in 21 CFR 1309.24(e) to include a statement that the threshold for retail distributions of ephedrine, pseudoephedrine and phenylpropanolamine is 24 grams in a single transaction, regardless of whether the product meets the definition of “ordinary over-the-counter pseudoephedrine or phenylpropanolamine product.” As MAPA amends those thresholds, as previously described, a conforming technical amendment to 21 CFR 1309.24(e) is being made to remove the reference to the 24 gram threshold.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. The requirements of MAPA included in this rulemaking were set out in such detail as to be self-implementing. Therefore the changes in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the law. Hence, DEA finds it unnecessary to publish for public notice and comment.

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will not adversely impact the public's access to drug products containing pseudoephedrine and phenylpropanolamine. At the same time, this regulation will limit the potential for diversion of these products to the clandestine manufacture of methamphetamine and amphetamine.