Consumer Healthcare Products Association
Food Marketing Institute
Healthcare Distribution Management Association
National Association of Chain Drug Stores

October 22, 2004

Administrator Karen P. Tandy
U.S. Drug Enforcement Administration
12060, 12th Floor
Lincoln Place-West
700 Army Navy Drive
Arlington, VA 22202

Docket No. DEA-211P; Proposed Rule: *Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropanolamine.* 69 Fed. Reg. 45616 (July 30, 2004).

Dear Administrator Tandy:

This letter is submitted on behalf of the Consumer Healthcare Products Association (CHPA), the Food Marketing Institute (FMI), the Healthcare Distribution Management Association (HDMA), and the National Association of Chain Drug Stores (NACDS). The purpose of the letter is to express our united concern that the Drug Enforcement Administration's (DEA's) proposed rule dated July 30, 2004, *Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropanolamine*[1] (proposed rule), is not supported by existing evidence and will impose a significant burden on the regulated industry.

Each of the organizations identified above represent companies that manufacture, distribute or sell over-the-counter (OTC) products containing List I chemicals regulated

[1] 69 Fed. Reg. 45616 (July 30, 2004).

by the Drug Enforcement Administration (DEA), that is, pseudoephedrine, ephedrine, and phenylpropanolamine. We have reviewed DEA's proposed rule - and each organization and many member companies plan to file written comments detailing our concerns by the close of the public comment period on October 28. However, prior to the close of comment period, we believe it important to summarize these concerns to alert the agency to the proposed rule's deficiencies.

Our primary concern is that DEA provides insufficient evidence to support a new regulation requiring additional security measures for manufacturers, distributors, importers and exporters of pseudoephedrine, ephedrine and phenylpropanolamine (PPA) products. The preamble to the proposed rule contains some theft information, and additional information has recently been placed on DEA's Web site. However, this information is substantially outdated and does not indicate a trend towards an increase in thefts from warehouses, especially those operated by our members. Further, many of the thefts cited took place under circumstances or in locations that are unrelated to the proposed requirements, and should not be used to support this rulemaking.

We are also in agreement that DEA has substantially underestimated the financial impact of the rule. The volume of products and the warehouse space needed to store them are far more than DEA estimates. The actual cost of installing the proposed physical security measures, such as cages, alarms, and monitors would be many times greater than the amounts stated in the proposed rule. Moreover, the proposal does not address additional expenses resulting from a final rule, including personnel, software revisions, new procedures, training, monitoring, and additional recordkeeping.

We are concerned that there will be other negative impacts from the rule that could affect the ability to ensure that necessary products reach the ultimate consumer in a timely manner. For example, does DEA have adequate field staff to review compliance actions without delaying registrations? Will warehouse staff be able to meet the same deadlines to provide these products from locations that will have to be locked and unlocked for entry and exit without increasing the very staff whose access should be limited? Although we appreciate the fact that the DEA staff have indicated they are open to alternatives, there has been no assessment of existing warehouse security methods which, we believe, negate the need for additional controls.

Consequently, we strongly recommend that the DEA withdraw the proposed rule. However, should DEA decide to proceed, we urge conducting a thorough evaluation of whether there is a need for the rule, based on theft trends in recent years and whether or not thefts from the locations covered by the rule are associated with the illicit manufacture of Methamphetamine. A comprehensive cost-benefit analysis is urgently needed.

We assure you that each of our organizations strongly support the DEA's product security goals. However, it is our collective belief that should DEA conduct our recommended assessments, the agency will find that the costs of the rule are significantly greater than estimated while providing negligible additional security. If we can provide additional information on this rule, please do not hesitate to contact either me, at 703-787-0000 ext. 219, or any of the Associations jointly submitting this letter.

Thank you for this opportunity to express our concerns.

Sincerely,

John M. Gray
President and CEO
Healthcare Distribution Management Association

Attachment

cc: Patricia Good
Docket No. DEA-211P
Eve Bachrach
Anita Ducca
Ty Kelly
Kevin Nicholson

Attachment

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