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September 20, 2004

BY FEDERAL EXPRESS

DEA Headquarters
Attention: DEA Federal Register Representative/CCD
2401 Jefferson-Davis Highway
Alexandria, Virginia 22301

Re: Docket No. DEA-211P

Dear Madam or Sir:

We submit these preliminary comments on behalf of the Consumer Healthcare Products Association (CHPA) in response to the proposed rule published on July 30, 2004 regarding security requirements for manufacturers, distributors, importers, and exporters of pseudoephedrine, ephedrine, and phenylpropanolamine.[1] These comments are limited to an important procedural issue raised by the notice of proposed rulemaking; CHPA's main substantive comments will follow at a later date. CHPA is the national trade association representing manufacturers and distributors of dietary supplement products and nonprescription, over-the-counter (OTC) medicines, including pseudoephedrine and ephedrine products. CHPA members account for over 90 percent of the retail sales of OTC medicines in the United States.

CHPA and its members share DEA's concerns regarding the diversion of pseudoephedrine, ephedrine, and phenylpropanolamine products. CHPA and member companies have worked closely with DEA over the years to prevent illicit diversion, and CHPA supports the appropriate regulation and control of these products. To these ends, CHPA is giving careful consideration to the new proposed security requirements. CHPA does not believe, however, that the notice of proposed rulemaking provides interested parties an adequate record to evaluate and comment upon the security measures DEA now proposes. In particular, the notice of proposed rulemaking fails to provide sufficient details regarding the thefts cited as the primary justification for requiring security requirements such as those for schedule III through V controlled substances. Unless corrected, the omission of

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

additional basic information about the instances of theft will prevent interested parties from fully evaluating and meaningfully commenting on the proposed security measures and possible alternate approaches.

DEA states in the notice of proposed rulemaking that its proposal is based upon "the number of reports and size of thefts from manufacturers and distributors of these chemicals," and cites numerous incidents of thefts of bulk chemicals and dosage units taking place between late 1995 and late 2003 as evidence of the need for security requirements such as those required for schedule III through V controlled substances.[2] According to DEA, current "limited security controls" and more effective controls on sales of these products have resulted in "an increasing number of thefts."[3]

The cited instances of pseudoephedrine, ephedrine, and phenylpropanolamine thefts thus are central to the proposed rule. However, the notice for the proposed rule provides scant details about the thefts. Most significantly, no details are given as to the dates of the particular thefts. Without such information, it is not possible to assess trends or patterns in the thefts, such as whether there has been a recent increase, or whether legislation limiting access to the products through legal channels, such as the Comprehensive Methamphetamine Control Act of 1996 and the Metamphetamine Anti-Proliferation Act of 2000, has led to rising thefts. The notice of proposed rulemaking also fails to provide any information as to the security controls in place at the affected facilities. This information is essential to evaluating the adequacy of existing security requirements under the regulations, DEA's proposed requirements, and alternate security measures.

Without additional basic information on the thefts that are at the center of DEA's proposed rule, the ability of CHPA and other interested parties to comment on the proposed rule will be significantly hampered. The Administrative Procedure Act (APA) requires that the public receive notice and a meaningful opportunity to comment on proposed regulations. This mandate includes public notice of the evidentiary record that forms the basis of an agency's proposed regulations.[4] Accordingly, if DEA does not provide further

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[2] *Id.* at 45616, 45618-19.

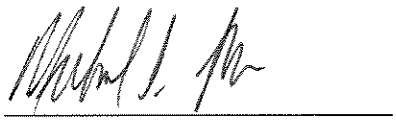
[3] *Id.* at 45617-18.

[4] 5 U.S.C. § 353; *Solite Corp.* v. *EPA*, 952 F.3d 473, 484 (D.C. Cir. 1991) ("Integral to the notice requirement is the agency's duty 'to identify and make available technical studies and data that its has employed in reaching the decisions to propose particular rules. . . . An agency commits serious procedural error where it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.'") (citations omitted); *Independent U.S. Tanker Owners Committee* v. *Lewis*, 690 F. 2d 908, 925-26 (D.C. Cir.
(continued...)

details on the thefts driving its proposed security regulations -- including in particular related to the dates of the thefts and the security measures in place at the facilities involved -- and extend the comment period to permit full consideration of the additional information, there will be a serious question as to whether the rulemaking comports with the APA.

CHPA and its members remain committed to working with DEA to minimize the diversion of products containing pseudoephedrine, ephedrine, and phenylpropanolamine, and recognize the importance of security controls as one key tool in the fight against diversion. CHPA thus looks forward to submitting substantive comments on the proposed security rule to assist DEA in its efforts. CHPA has requested the additional information described here, and an accompanying extension of the comment period, so that the comments the association and other interested persons submit on these issues are as informed as possible.

Respectfully submitted,



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Kelly A. Falconer

Counsel to the Consumer Healthcare Products Association

cc: Cynthia R. Ryan, Esq.
Chief Counsel, Drug Enforcement Administration

1982) (invalidating agency rule and application decision where agency based its analysis on, and drew its conclusions from, a set of forecasts without disclosing them to the parties for comment upon the conclusions properly to be drawn from them).