FOOD MARKETING INSTITUTE

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October 28, 2004

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

Re: Security Requirements for Pseudoephedrine, Ephedrine, and Phenylpropanolamine (Docket No. DEA-211P)

Dear Sir or Madam:

The Food Marketing Institute[1] (FMI) respectfully submits the following comments in response to the Drug Enforcement Administration's (DEA's) proposal to amend 21 CFR, Part 1309 to require manufacturers, distributors, importers and exporters of pseudoephedrine, ephedrine and phenylpropanolamine to implement new security requirements to prevent the theft and diversion of these List I chemicals. 69 Fed. Reg. 45616 (July 30, 2004).

Although FMI certainly supports the overall goal of increasing the security of List I chemicals, the proposed regulation is overly broad and burdensome. As discussed more fully below, the case studies cited by DEA in the preamble to the proposal[2] demonstrate that any problem that exists occurs at facilities that handle bulk containers (*e.g.*, 1000 count bottles) of the products, rather than blister packs or other individual, consumer-ready packaging of cough and cold medicine. The consumer packaged products are less attractive for theft or diversion and are clearly protected by the extensive security systems

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies—food retailers and wholesalers—in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with combined annual sales of $340 billion –three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-state chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 foreign countries.

[2] Actually, the information contained in the preamble is quite limited. As a result of further contact with the Agency we were able to obtain the attached document that provides somewhat greater information about the occurrences upon which DEA is relying to justify the proposal. Although far from detailed, nothing in either the preamble or the additional DEA summary in any way suggests that thefts of consumer-ready packages of cough and cold medicine are occurring at supermarket distribution centers and warehouses.

implemented at supermarket distribution centers and warehouses on a voluntary basis as provided for under the current regulations. Therefore, as discussed more fully below, we urge DEA either to withdraw the proposal or to promulgate a final regulation that includes an exemption for distribution centers, warehouses and other similar facilities that only handle these cough and cold medicines in blister packs or other individual consumer-ready packaging.

A. Existing Security Measures Employed at Supermarket Industry Distribution Centers and Warehouses Are Highly Effective for Preventing Theft of Cough and Cold Medicine

As DEA knows, FMI and its members are very concerned about the theft and diversion of List I chemicals. Over the years following Congressional enactment of the Comprehensive Methamphetamine Control Act (P.L. 104-237), the supermarket industry developed and strengthened a strong and cooperative working relationship with DEA. Reflective of this ongoing partnership, FMI member companies have initiated numerous voluntary measures at both the wholesale and retail level to minimize and prevent the loss of over-the-counter (OTC) medications that contain either pseudoephedrine or ephedrine. As a result, we believe that our segment of the wholesale and retail sector has significantly increased the safety and security surrounding the handling, distribution and sale of consumer cough and cold products that contain these chemicals.

Following publication in the Federal Register of the proposed regulations by DEA, FMI surveyed its membership for information on current practices to secure cough and cold medicines and on incidents of significant thefts of OTC cough and cold products from their warehouses and distribution centers. Twenty-nine companies, operating 153 DEA-registered warehouses, responded to our questionnaire. On the key question regarding the loss of cough and cold medications, ***none of our members stated that they had experienced any major thefts of these products from their facilities over the past three years.***

The FMI questionnaire further asked our members what types of security measures they have instituted to protect "theft-sensitive" products. The responses were quite revealing, demonstrating that FMI member companies currently rely on many different security systems to protect products from theft and diversion at the wholesaler-distributor level. FMI found that a significant number of supermarket distributors utilize monitored alarm systems as well as closed circuit surveillance cameras in their distribution facilities. Others have installed electronic detection or alarm systems.

While a number of respondents indicated that they have a cage or safe in their warehouse, they noted that their cages and safes are not large enough to handle the large

volume of affected cough and cold products that are shipped to the facility.[3] For example, some respondents store cartons of cigarettes in cages, but the DEA proposal might not permit storage of non-regulated chemicals, such as cigarettes, with products containing List I chemicals in the same cage, absent permission from the agency. These same respondents further noted that their cages are probably not large enough to handle the storage of both cigarettes and OTC medications.

Furthermore, all respondents restrict public access to their warehouses and have security procedures in place for handling business guests, vendors, maintenance personnel, outside contractors and other individuals in areas of the facility where List I chemicals are stored. With few exceptions, all respondents routinely conduct criminal background checks of applicants who will be working in their warehouses and distribution centers. A large number of firms stated they have pre-hire and random drug testing programs at the warehouse level.

Moreover, many of the respondents indicated that their warehouses have a security checkpoint and that they conduct random or routine inspections of packages or bags carried by employees and other individuals as they leave the facility. Many respondents said that cough and cold products are always placed and shipped in sealed shipping containers or totes. All shipments and deliveries are inventoried prior to loading onto trucks and verification of inventory is also conducted upon delivery to stores. Once-a-week cycle counts are prevalent among distribution centers that handle OTC medications to identify any possible discrepancies.

Truck trailers are sealed and the seal is inspected before the truck leaves the warehouse premises or compound. Every respondent also has procedures in place to limit access to the warehouse facility, such as a guarded entrance, roving security patrols and fencing surrounding the perimeter of the property. Several companies noted that they conduct random checks of vehicles that are leaving the warehouse compound. In summary, FMI member companies typically *and effectively* use multiple security measures to combat the theft of cough and cold products from their distribution facilities, without cages or safes.

B. DEA's Proposal Is Overly Broad and Would Impose Requirements Disproportionate to the Benefit

Notwithstanding the commitment of FMI and its members to security surrounding pseudoephedrine and ephedrine products, we have significant reservations regarding DEA's most recent proposal. Although well-intentioned, the proposal is overly broad and would impose disproportionate costs on facilities, such as grocery warehouses and distribution centers that only handle cough and cold medicines that are already in

[3] Consumer-packaged products inevitably require greater storage space than bulk containers of pharmaceuticals because each consumer-sized quantity is enclosed in its own packaging, e.g., blister packs and boxes, which adds substantially to the space required to store the products.

consumer-sized packages. As discussed more fully below, neither DEA nor our survey has adduced any evidence that significant thefts of cough and cold medicines are occurring at supermarket distribution centers or warehouses, which only handle cough and cold medicines in consumer-packaged formats. The true costs of the security measures proposed by DEA – particularly the requirement to install cages or safes – are exceptionally high. Since no problem has been identified for these measures to solve at the retail industry distribution center level, no benefit will accrue and, therefore, the costs are unnecessary and disproportionate.

1. Thefts Documented by DEA Do Not Involve Consumer-Ready Packages of Cough and Cold Products from Supermarket Distribution Centers and Warehouses

DEA relies upon several recent incidents of theft to support the proposed increase in mandatory security measures. 69 Fed. Reg. at 45618. The preamble to DEA's proposed rule briefly identifies 38 incidents of thefts of pseudoephedrine and ephedrine from various facilities. Id. at 45618-19. As the preamble treatment of these events is cursory, FMI sought further information from DEA. In response, DEA provided the attached summary, which sets forth some additional information about each of the events noted in the preamble.

None of the information that DEA has presented implicates supermarket warehouses or distribution centers that only handle consumer-sized packages of cough and cold medicines. Specifically, 27 of the 38 theft reports were from facilities that are clearly not traditional grocery wholesalers or company distribution centers, but rather chemical manufacturers, chemical distribution companies, importers, a repack/relabeling facility, and others Of the remaining eleven referenced thefts in the rulemaking, it is difficult to ascertain the type of distributor that reported the theft, but the narrative description seems to suggest that these facilities are not likely from our industry. For example, thefts were reported by a hospital distribution center, several pharmaceutical distributors, and a mail order pharmacy among others.

The descriptions of the products stolen in these thefts further suggests that these were not consumer-ready packages. For example, Bullet #31 relates theft of "1,440 bottles containing 120 tablets per bottle and 2,304 bottles containing 60 tablets per bottle for a total of 311,040 60 mg tablets" from a "small distributor." Clearly, however, this was not a supermarket distribution center as retail supermarkets do not carry bottles with 120 or 60 tablets of pseudoephedrine; they only handle consumer-ready packages, such as blister packs, which might hold 24 individually wrapped tablets. Similarly, Bullet #19 addresses thefts of 1000-count bottles of pseudoephedrine and ephedrine and Bullet #20 addresses thefts of 100-count bottles. Some of the information DEA provided is not complete enough for the public to make an accurate determination but in no case has DEA provided any evidence that thefts have occurred at supermarket distribution centers or warehouses that carry only consumer-sized packages of cough or cold medicine.

2. DEA Significantly Underestimated Actual Costs of Proposed Security Measures By Failing To Consider Many Practical Costs

The DEA proposal would be extremely expensive if implemented in its current form. For example, while some of our wholesaler members have cages and/or safes, and in some cases a secure room, these more secure areas of the facility do not have the physical capacity to store significant amounts of cough and cold products. Thus, these firms would have to "bump out" their cages or construct new cages.

DEA estimates that it would cost $2,400 to $3,600 for each distributor to construct a cage, and $2,100 to $4,190 to purchase and install an alarm system. FMI disagrees with the DEA estimates based on cost estimates provided to FMI by our wholesaler members. Many FMI members responded that they thought DEA's estimate on just the construction costs of the cage were too conservative and said that cages built to the proposed specifications could cost as much as $15,000 or more per cage.

Aside from the baseline costs of constructing a cage and installing an alarm system, the DEA estimate fails to consider several other highly significant cost factors. These costs include the loss of square footage in the warehouse to accommodate new cages, the need to reconfigure the lay-out of the distribution facility, segregation of cough and cold products from "pick lines" to secure areas, lost productivity based on product segregation, additional staffing requirements and costs associated with re-writing computer programs.

One FMI member company stated that an 800 cubic foot cage, which DEA used to develop its cost estimates, would not be sufficient or workable from an operational standpoint. This particular firm, which handles significant quantities of merchandise, said they would need a much larger structure for placing OTC medications in a cage and for accommodating new product positioning. As such, this would result in the loss of one percent of capacity space at their facility, or approximately 2700 square feet. The company estimates its square footage cost at $30 which translates to $81,000 in lost capacity space per facility.

Another FMI member company that operates a warehouse estimates the DEA regulatory proposal would be significant, including $200,000 to reconfigure and "bump out" the cage and to locate the structure in close proximity to the facility's conveyor system. This firm further estimated software changes at about $50,000 while annual labor costs would increase by some $250,000 annually because of the loss of productivity associated with retrieving cough and cold medicines from an area segregated from the rest of the products that would be selected from the warehouse for distribution to a supermarket.

Another company provided FMI with an estimate that, if the DEA rulemaking eventually required cough and cold products to be kept in cages, safes or secure rooms, it would result in a cost increase of 25 cents per handled unit or package. Quite a few companies "ball parked" the annual cost of the DEA proposed rulemaking at between $100,000 to $200,000 per facility. Other costs estimates ranged from $50,000 to $250,000 annually per facility. Thus, the cost estimates that FMI has received from our member companies are substantially higher than those provided by DEA in its proposal because DEA failed to consider the true costs of the proposal, including the loss of valuable real estate and the significant decline in productivity and efficiency attributable to the segregation of one class of products from the rest of the products that are selected for distribution to individual supermarkets from the warehouse.

C. Compliance Deadline for New Security Requirements

The DEA proposed rulemaking suggests that affected parties would have 120 days in which to comply with the new security requirements following the issuance of a final rule. The DEA regulations further contemplate some type of "alternate arrangements" for companies that are making a good faith effort to comply but who would be unable to meet the regulatory deadline. FMI has asked our member companies whether they could meet a 120-day deadline as specified in the proposed rule. Most companies felt that 120 days was insufficient, especially in terms of cage construction, corresponding alarm systems, floor reconfiguration and other logistical issues that would have to take place in facility that is actively receiving and shipping merchandise on a daily basis. Additionally, time would be needed to reprogram computers and software systems, and to tests these system to determine their functionality. As such, our members felt that they would need a minimum period of one year in which to comply with DEA's new security requirements.

D. Conclusion: FMI Recommends Affirmative Exemption from Proposed Security Measures for Supermarket Distribution Centers and Warehouses That Only Handle Cough and Cold Medicines in Consumer-Read Formats

Based on the foregoing, FMI recommends that DEA either withdraw the proposal or include an affirmative exemption from the increased security measures in the final rule for supermarket distribution centers and warehouses or similar facilities that only handle cough and cold medicines in consumer-ready formats. Alternatively, FMI recommends that DEA continue to rely upon its current physical security measures for distributors, such as grocery wholesalers and supermarket companies that operate self-distributing warehouse facilities. The DEA physical security measures for distributors are comprehensive without sacrificing flexibility. These security measures are clearly effective as neither DEA nor FMI has found evidence of any major thefts of cough and cold products from our members' distribution facilities. If a major theft were to occur at

a warehouse, DEA should conduct an inspection of the facility and provide the registrant with recommendations for corrective action on where security needs to be improved.

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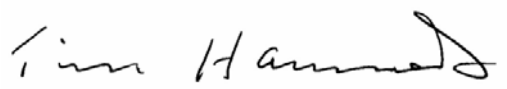
FMI appreciates the opportunity to participate in this important regulatory proceeding. Our industry will maintain its commitment to provide extensive security measures at the warehouse level and to evaluate these systems continually so that OTC medications containing List 1 chemicals are safe and secure from theft and diversion. We hope that DEA will adopt the recommendations set forth above and modify its rulemaking accordingly to reflect our comments.

Sincerely,



Tim Hammonds
President and CEO

Enclosure: DEA incident summary