

# COVINGTON & BURLING

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October 28, 2004

## **BY FIRST CLASS MAIL**

Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration  
Washington, DC 20537  
Attention: DEA Federal Register Representative/CCD

**Re: Docket No. DEA-211P**

Dear Madam or Sir:

We submit these 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.<sup>1</sup> These comments supplement the joint comments CHPA submitted with three other leading trade associations on October 22, 2004, and CHPA's preliminary comments of September 20, 2004, which addressed procedural concerns raised by the lack of information in the notice of proposed rulemaking concerning the factual record on which the proposal is based.

CHPA is the national trade association representing manufacturers and distributors of dietary supplement products and nonprescription, over-the-counter (OTC)

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<sup>1</sup> 69 Fed. Reg. 45616 (July 30, 2004).

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medicines, including pseudoephedrine and ephedrine products.<sup>2</sup> CHPA members account for over 90 percent of the retail sales of OTC medicines in the United States, and have a vital stake in the security requirements DEA has proposed.

CHPA and its members share DEA's concerns regarding the diversion of pseudoephedrine, ephedrine, and phenylpropanolamine products. CHPA and member companies have thus worked closely with DEA over the years to prevent illicit diversion, and have been proactive in adopting measures to ensure the safe and secure handling of these chemicals. While CHPA supports the appropriate regulation and control of these products, CHPA respectfully submits that DEA has failed to establish that the new security requirements are needed.

The evidentiary record DEA has produced does not show a growing theft problem for these listed chemicals, and there is no nexus between the facts DEA cites and the highly rigid and detailed security measures it proposes. To the contrary, the available facts suggest that what is needed, if anything, at present is enforcement of existing security requirements. Moreover, critical aspects of the proposed requirements are unrealistic and unworkable. CHPA thus urges DEA to withdraw the proposed rule and reconsider the available evidence. If there are thefts beyond those DEA has presented to date, then it may be appropriate to create new legal requirements, but any such requirements must be tailored to the factual evidence in a way that the current proposal is not.

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<sup>2</sup> As DEA notes in the notice of proposed rulemaking, FDA has taken action to remove phenylpropanolamine (PPA) from the market. In response, many companies reformulated their products and discontinued selling products containing PPA. *Id.* at 45616.

CHPA's strong view is that there is not now a basis for imposing new security. If DEA nonetheless moves forward with this rulemaking, modifications should be made before any final rule is adopted. The modifications would provide needed flexibility for the legitimate industry without compromising the security goals that DEA seeks to meet. More detailed comments on these points follow.

**I. The Available Factual Record Does Not Support the Proposed Requirements.**

The factual record DEA has produced to justify the new measures is extremely limited. The proposed rule is premised on "the number of reports and the size of thefts from manufacturers and distributors of" pseudoephedrine, ephedrine, and phenylpropanolamine.<sup>3</sup> However, the notice of proposed rulemaking and the supplemental information DEA posted on the Internet<sup>4</sup> only provide information on 38 incidents of thefts between March 1996 and January 2003. Many of these instances are far removed from DEA's expressed concerns about the storage of bulk chemicals and dosage units by manufacturers and distributors.

For example, some thefts occurred in analytical laboratories or from trailers parked off the registrant's premises. Others instances resulted from open storage areas, unsecure cages, or non-functioning security cameras, all of which could be addressed within DEA's existing security regulations by measures far short of those DEA now proposes. Yet other examples are reported by DEA as unexplained, and thus also do not support the highly

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<sup>3</sup> *Id.*

<sup>4</sup> <<[http://www.deadiversion.usdoj.gov/fed\\_regs/rules/2004/fr0730\\_summary.htm](http://www.deadiversion.usdoj.gov/fed_regs/rules/2004/fr0730_summary.htm)>> ("DEA Diversion Website").

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prescriptive requirements in the proposed rule. These isolated incidents resulting largely from lapses in security controls, and taking place primarily in years past, do not demonstrate the need for adopting the stringent security measures applicable to schedule III through V controlled substances. Nor do they establish that some alternative short of what DEA proposes would be ineffective to prevent future thefts, including enforcement of the existing regulations.

DEA offers no statistics to establish a growing theft problem or trend. Indeed, the record contradicts any claim that thefts have increased due to enactment of the Comprehensive Methamphetamine Control Act of 1996 and the Methamphetamine Anti-Proliferation Act of 2000. Of the 38 specific incidents cited, only 10 thefts have occurred since 2001: 2 reported thefts in 2003, 5 in 2002, and 3 in 2001.<sup>5</sup> Even if DEA could demonstrate an increase in the number of thefts, which it has not, in order to show a real rising theft problem it would be necessary to show an increase in thefts relative to the number of registrants and/or the volume of product in commerce. No showing along these lines has been made.

The notice of proposed rulemaking describes the security measures required under current law as being “minimal.”<sup>6</sup> That characterization is not fair or accurate. The existing regulations mandate that DEA ensure that security controls and procedures are effective by evaluating for a given registrant (1) type, form, and quantity of chemical

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<sup>5</sup> DEA Diversion Website.

<sup>6</sup> 69 Fed. Reg. at 45619.

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handled; (2) location of the premises and the relationship between the location and security needs; (3) type of building and general characteristics of the building; (4) availability of electronic detection and security alarm systems; (5) extent of unsupervised public access; (6) adequacy of supervision over employees; (7) procedures for guests/visitors; and (8) adequacy of system for monitoring the receipt, distribution, and disposition of List I chemicals.<sup>7</sup>

The current regulations specifically require that the chemicals be “stored in containers sealed in such a manner as to indicate any attempts at tampering,” and when that is not possible that access be controlled through physical means or human/electronic monitoring.<sup>8</sup> Registered distributors and manufacturers of list I chemicals must also exercise caution in hiring employees who will have access to listed chemicals, including by taking into account whether they have been convicted of a felony relating to controlled substances or listed chemicals, have ever had an application for DEA registration denied, or revoked, or have surrendered a DEA registration for cause.<sup>9</sup> Registrants further are expected to take action, independent of federal or state prosecution, against an employee who possesses, sells,

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<sup>7</sup> 21 C.F.R. § 1309.71(b).

<sup>8</sup> 21 C.F.R. § 1309.71(a)(1).

<sup>9</sup> 21 C.F.R. § 1309.72(a). Some CHPA members go a step further and perform background checks of any employee who is likely to handle such products.

uses, or diverts listed chemicals or controlled substances,<sup>10</sup> and should maintain confidential “whistleblower” mechanisms for employees to report diversion by fellow employees.<sup>11</sup>

CHPA represents 90 percent of industry and a recent informal survey of its members identified few thefts of any significance, due in large part to the security measures required in the current regulations. When companies have experienced instances of theft, they have implemented new security measures and those measures have been effective. No member company reports more than isolated instances of theft in the past three years, and the majority of companies have had no thefts at all. This survey, although admittedly not exhaustive, along with the supplemental information DEA has provided, indicates that there is not a material theft problem at mainstream manufacturers of OTC medicines containing pseudoephedrine, ephedrine, or phenylpropanolamine.

In making these observations CHPA does not mean to suggest that the problem of thefts and diversion is not real or important. However, the administrative record does not make the case that the rigid and inflexible requirements DEA has proposed are necessary at this time. Available evidence suggests that DEA has ample authority through enforcement of the existing regulations to address the identified security concerns. To the extent DEA disagrees, it is incumbent upon DEA to demonstrate in a careful way how any new security measures it imposes are supported by and tailored to the actual instances of theft it has observed in its law enforcement and regulatory activities.

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<sup>10</sup> 21 C.F.R. § 1309.72(b).

<sup>11</sup> 21 C.F.R. § 1309.73.

## **II. The Proposed Requirements are Unworkable.**

The proposed security controls are highly specific, and the only mechanism to gain acceptance for alternate approaches is administratively burdensome and otherwise problematic. This lack of flexibility provided registrants in developing effective controls against diversion appears to be based in large part on a flawed analogy to Schedule III through V controlled substances, which does not fit mass market products such as the OTC medicines at issue here. The proposal grossly underestimates the cost and time that would be involved in implementing the new measures, providing an additional basis to withdraw and rethink the proposed rule.

### **A. The Proposed Security Requirements are Overly Rigid.**

DEA has itself recognized the distinctiveness of list I chemicals and the need for flexibility in crafting security controls for such products. In the preamble to the final rule establishing its current security requirements for listed chemicals, DEA explained that

List I chemical handlers vary greatly in size, type of business and volume handled. Under such circumstances, it would not be desirable to establish specific, inflexible security controls and procedures. The factors outlined in Section 1309.71(b) provide a general framework of elements that allow potential registrants flexibility in assessing the potential threat of diversion and to determine measures necessary to prevent diversion.<sup>12</sup>

The need for flexibility in the security requirements for listed chemicals remains today even with any new security threats that have emerged. New threats need to be met, to be sure, but

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<sup>12</sup> 60 Fed. Reg. 32447, 32450 (June 22, 1995).

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in a way that also takes into account the objective of avoiding “specific, inflexible security controls and procedures.” The current proposal fails in this regard and is flatly inconsistent with DEA’s previously articulated approach.

Proposed section 1309.74 provides only three specific options for the secure storage of pseudoephedrine, ephedrine, and phenylpropanolamine: (1) a safe or steel cabinet, permitted only for quantities of less than 1.0 kilogram, (2) a secure room with perimeter security, and (3) a cage.<sup>13</sup> Exact specifications are detailed for each option:

- Safes and steel cabinets must be effective against 30 man-minutes surreptitious entry, 10 man-minutes forced entry, 20 man-hours lock manipulation, and 20 man-hours entry radiological techniques, and must be bolted or cemented to the floor or wall if weighing less than 750 pounds.<sup>14</sup>
- Secure rooms must have perimeter security that limits access during working hours and provides security after working hours, as well as self-closing and self-locking doors or doors that are kept locked when not in use and otherwise are under direct observation.<sup>15</sup> Any hinges on doors to secure rooms must be mounted on the inside of the room or be sealed, welded, or otherwise built to inhibit removal, and locking devices for such doors must be either multiple-position combination or key lock.<sup>16</sup>
- Cages must be built with not less than No. 10 gauge steel fabric mounted on steel posts that are at least one inch in diameter, set in concrete or installed with lag

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<sup>13</sup> Proposed 21 C.F.R. § 1309.74(a).

<sup>14</sup> Proposed 21 C.F.R. § 1309.74(c).

<sup>15</sup> Proposed 21 C.F.R. § 1309.74(d).

<sup>16</sup> *Id.*



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bolts that are pinned or brazed, and placed not more than ten feet apart with horizontal reinforcements every sixty inches.<sup>17</sup> The cage must also have meshed construction with openings of not more than two and one-half inches across, a ceiling that is made of the same material or that reaches and is securely attached to the structural ceiling of the building (except that lighter gauge mesh may be used for ceilings if the walls are at least 14 feet in height), and a door constructed of No. 10 gauge steel fabric on a metal frame in a metal door flange meeting the same locking requirements as for secure rooms with perimeter security.<sup>18</sup>

- All storage areas except safes and steel cabinets with less than 1 kilogram of regulated inventory must be equipped with an alarm system linked to a central monitored location.<sup>19</sup>

Under the proposed rule, the only way to employ alternate security measures is to obtain DEA approval.<sup>20</sup> This option provides some flexibility, but is inadequate. First, the need to obtain specific approval for any alternate security measures would be administratively burdensome and time consuming, both for registrants and for DEA. Second, if decisions on alternate proposals are decided by field offices on a case by case basis, there is real risk that inconsistent standards will be applied. These concerns are particularly great because CHPA anticipates based on a survey of its membership that the overwhelming majority of manufacturer registrants would seek approval of modified security measures.

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<sup>17</sup> Proposed 21 C.F.R. § 1309.74(e).

<sup>18</sup> *Id.*

<sup>19</sup> Proposed 21 C.F.R. § 1309.74(a), (b).

<sup>20</sup> Proposed 21 C.F.R. § 1309.74(a), (f), (g).

The three specific options in the proposed rule are simply not workable or economically viable for many manufacturers, for reasons discussed next.

**B. DEA's Cost Estimate is Unrealistically Low.**

The proposed rule grossly underestimates the costs and time that would be associated with implementing the new security measures. The cost estimates in the proposed rule are based in part on a misapplied analogy to the handling of controlled substances. This analogy fails to take into account the seasonal shifts in inventory that occur with many OTC products containing ephedrine, pseudoephedrine, and phenylpropanolamine, as well as the fact that these are mass consumer products.<sup>21</sup>

Schedule III through V controlled substances generally are used for small vials or bottles of prescription drugs. In contrast, the list I chemicals at issue here are manufactured into OTC packages and cartons for consumers, and are produced, stored, and shipped in far greater volumes. Moreover, whereas scheduled substances are generally manufactured and inventoried at fairly constant levels, many of these OTC products are seasonal. Manufacturer and distributor inventory constantly fluctuates for cold and sinus medications such as those containing pseudoephedrine, ephedrine, and phenylpropanolamine, and levels are much higher at peak allergy and cold seasons.

Based in part on these key differences with Schedule III through V controlled substances, CHPA's members estimate that the proposed measures will be significantly more expensive than estimated. For example, the notice of proposed rulemaking estimates that it

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<sup>21</sup> 69 Fed. Reg. at 45620-21.

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will cost between \$2,400 and \$3,670 to purchase and install cages, the least expensive of the proposed storage options.<sup>22</sup> This estimate is based upon an 800 cubic feet cage, apparently rooted in the misconception that “most distributors are not storing large quantities of these products at any one time.”<sup>23</sup> In fact, CHPA member warehouse facilities store finished pseudoephedrine in warehouse spaces that are hundreds of thousands of square feet and in which pallets are constantly moving on a first-in, first-out basis.

Members sometimes have thousands of pallets of finished product on hand at any given point in time, with an inventory for the largest manufacturers of up to nearly 20,000 pallets. In addition to finished product, the largest manufacturing facilities dealing with bulk raw material sometimes have tens of thousands of kilograms of raw material on site, as well as substantial quantities of work in process. DEA’s cost projection for cages is thus based upon an unrealistically low volume estimate. According to CHPA members, a low estimate is that just the materials for constructing a standard cage would run some \$50,000. Neither this figure nor the DEA estimates include other ancillary security costs (such as monitoring, additional personnel, maintenance, etc.).

One large manufacturer estimates that the cost of creating the required cages within existing logistics (i.e., distribution) sites and associated security for that company alone would cost between \$5.4 million and \$11 million, with an average per pallet cost of \$645. According to the company, this figure does not reflect the costs for manufacturing

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<sup>22</sup> *Id.* at 45620.

<sup>23</sup> *Id.*

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facilities. The company estimates that additional DEA cage space for just one of its manufacturing facilities would run between \$180,00 and \$451,000.

Similarly in the case of alarm systems, which DEA estimates at between \$2,100 and \$4,190, prior company experience suggests that surveillance cameras/alarm systems would cost significantly more for those companies that do not outsource security monitoring. Moreover, DEA's estimate fails to reflect the further expense of additional personnel that would be needed in connection with the operation of such systems.

More generally, the proposal fails to take into account, among other things, (1) the additional handling costs associated with picking orders and packing from a cage dedicated to pseudoephedrine-containing products, (2) the lost storage capacity that would result from the prohibition against non-segregated storage, (3) the cost of additional warehouse space for non-pseudoephedrine products because cage space would no longer be available for general storage, and (4) the costs to third party vendors with independent warehouses. One large manufacturer estimates that the all-in estimated costs to meet the proposed rule for that company would be just shy of \$50 million, taking into account the materials needed for the handling of raw materials, work-in-process, and warehousing; additional work force; other security and maintenance costs; new freight costs; etc.

These added costs will be borne not only by manufacturers but also by centralized retail distribution centers such as those used by chain stores for distribution to individual retail outlets. In light of the additional manufacturing and distribution costs that will be incurred for products containing these listed chemicals, there is no realistic basis for

DEA's assumption that its proposal will not have an impact on cost and access for consumers of OTC medicines.

**III. If the Rule is Not Withdrawn, Critical Modifications Must be Made.**

For the reasons set forth above, CHPA urges DEA to withdraw and reconsider the proposed rule based on more careful evaluation of the evidence. If DEA nonetheless moves forward, the rigid and burdensome approach of the proposed rule must be modified in several respects to add flexibility, flexibility that the DEA itself has previously recognized as important for listed chemical handlers and that is at the same time consistent with the prevailing security imperatives.

**A. An Additional Security Option Should be Established.**

Based on the foregoing concerns, CHPA proposes that DEA establish an additional category of security measures that a facility could follow to be considered a secure storage area without the need for prior DEA approval. The additional category would be enumerated in the regulations as a new subsection in the proposed 1309.74.

The specific parameters of this new proposed security option are based on measures many CHPA member companies have employed with a proven track record in preventing theft and diversion, and would work in conjunction with the employee screening provisions in the existing regulations. Following is sample regulatory language for what CHPA is proposing:

§ 1309.74() Manufacturers, distributors, importers, and exporters of pseudoephedrine, ephedrine, and phenylpropanolamine will be considered to have adequate

security measures and meet the requirements of this section if, at minimum, any building in which the pseudoephedrine, ephedrine, and phenylpropanolamine is stored and processed complies with the following:

- (1) The building is secured by three or more of the following measures:
  - (i) perimeter fencing or an alternate secure barrier;
  - (ii) exterior closed circuit television cameras;
  - (iii) security guards on site 24 hours a day, 7 days a week;
  - (iv) limited access (e.g., card access) for all entrances and exits other than fire exits, with alarmed exits; and
  - (v) visitor check-in and escort requirements for areas where chemicals are stored or processed.
- (2) Raw materials awaiting processing or shipping are stored in secure areas meeting the requirements of 1309.74(c), (d) or (e).
- (3) During non-production periods, work-in-process is monitored by closed circuit television cameras or designated responsible employees.
- (4) Inventory tracking and sample cycle counts are routinely performed.
- (5) Shipping and receiving areas:
  - (i) have procedures in place to ensure inbound and outbound shipments have been authorized;
  - (ii) include designated waiting areas for truck drivers; and
  - (iii) prohibit loading after operating hours for that facility, unless approved by management and properly supervised.

These measures are examples of rigorous protection mechanisms that could be instituted against theft and diversion but that would provide important additional flexibility to manufacturers.

**B. A Modest Quantity Threshold Should be Established to Trigger Security Requirements.**

As proposed, DEA's regulations for special security measures for pseudoephedrine, ephedrine, and phenylpropanolamine would apply to facilities housing such products regardless of the amount of product stored. The lack of any threshold to trigger these security measures is problematic. For example, as written, the proposal could apply to sales representatives who transport or carry physician drug samples. At a minimum, DEA should amend the proposed rule to include a volume threshold under which the new, special security requirements would not apply.

CHPA proposes that language along the following lines be added at the end of proposed section 1309.74(a):

The security requirements in this section do not apply if a total of less than 150 grams combined pseudoephedrine, ephedrine, and phenylpropanolamine base is being stored at one time at a particular location.

This additional language would modify the reach of DEA's proposal and make compliance less onerous for entities or persons storing very small quantities of products.

**C. Commingling of Regulated and Nonregulated Products Should be Permitted with Controls.**

Unless the relevant field office approves commingling, the proposal would preclude the storage of pseudoephedrine, ephedrine, and phenylpropanolamine with nonregulated chemicals and other materials.<sup>24</sup> There is no basis for this restriction. The end

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<sup>24</sup> Proposed 21 C.F.R. § 1309.74(h).

result of commingled storage would be more stringent security for nonregulated products, not diminished security for the regulated products.

Moreover, for products such as pseudoephedrine, ephedrine, and phenylpropanolamine commingled storage with nonregulated products is necessary to allow for more efficient use of space during non-peak seasons given shifts in inventory and seasonality. Thus, there would be a widespread need to obtain permission for commingling. Requiring permission for commingling in turn would be burdensome and would risk inconsistent treatment. As discussed above, product inventory is constantly changing and repeated requests for approval would be crippling to logistical operations for facilities managing regulated and nonregulated products. Additionally, different field offices and different personnel might apply varying standards. This could result in inconsistent security standards for different manufacturers and distributors and even different standards for separate facilities owned by a single company.

DEA should amend any final rule to permit these list I products to be stored with nonregulated substances without prior approval. CHPA proposes that DEA amend proposed section 1309.74(g) to read as follows:

Nonregulated chemicals and other materials may be stored with pseudoephedrine, ephedrine, and phenylpropanolamine in any of the secure storage areas required by this section. There shall be a presumption that non-segregated storage will not diminish the effectiveness of security measures and such storage shall thus not require DEA approval. Non-segregated storage shall be permitted absent a finding from DEA that such non-segregated storage will diminish the effectiveness of security for pseudoephedrine, ephedrine, and phenylpropanolamine.



**D. Access to Storage Areas Should be More Appropriately Limited.**

Under proposed section 1309.74(i), access to pseudoephedrine, ephedrine, and phenylpropanolamine storage areas must be made accessible to “an absolute minimum number of specifically authorized employees” and when others must be present or pass through such areas, “the registrant must provide for adequate observation of the area by an employee specifically authorized in writing.”<sup>25</sup> The intent of this subsection appears to be restricting access of storage areas to authorized personnel only. Although CHPA certainly supports the goal of restricted access, DEA’s proposal as written is too vague to be applied. Moreover, it would impose an undue burden by requiring not only that unauthorized personnel be observed, but that there be written authorization of the observing employee.

To meet DEA’s goal of limiting storage areas to authorized personnel without placing an unnecessary obligation on manufacturers and distributors in those situations when others must enter such areas, CHPA proposes that DEA amend proposed section 1309.74(i) as follows:

Access to the pseudoephedrine, ephedrine, and phenylpropanolamine storage areas must be restricted to authorized personnel. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through pseudoephedrine, ephedrine, and phenylpropanolamine storage areas, the registrant must have adequate procedures in place to prevent theft or diversion of product.

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<sup>25</sup> Proposed 21 C.F.R. § 1309.74(i).

This approach would provide affected entities greater flexibility to craft workable procedures to limit access to storage areas as well as opportunities for diversion.

**E. Clarification is Needed on the Rules for Storage in a Safe or Steel Cabinet.**

Proposed section 1309.74(c) states that where small quantities (less than one kilogram of pseudoephedrine, ephedrine, or phenylpropanolamine, combined) permit, the chemicals may be stored in a safe or steel cabinet meeting appropriate specifications. This proposed regulation thus seems to limit the use of safes or steel cabinets to the storage of less than one kilogram of total material. However, proposed section 1309.74(a) states that a safe or steel cabinet must have an alarm system if a total of one kilogram or more of chemicals is stored at any one time. This suggests that more than one kilogram may be stored in a safe or steel cabinet, provided it has an alarm. Clarification is thus needed on the amounts of pseudoephedrine that may in fact be stored in a safe or steel cabinet.

**F. Additional Time Should be Provided for Implementation.**

The implementation period in the proposed rule is wildly unrealistic. If the proposal is finalized, DEA intends to give manufacturers, distributors, importers and exporters until "90 days after the effective date of the final rule to install the security systems. The final rule will become effective 30 days after publication in the Federal Register."<sup>26</sup> This would provide affected parties a total of 120 days to implement compliant security systems. Where despite a timely and good faith effort to comply, an affected entity

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<sup>26</sup> 69 Fed. Reg. at 45621.

is unable to meet the deadline, DEA would require the entity to notify the local DEA office “to make alternate arrangements in the interim.”<sup>27</sup>

These timelines are simply not workable, particularly once the true scope of required work is taken into account, as discussed in detail above in connection with the costs of the new security measures. CHPA members estimate that it would take at least 12 months to implement the new security requirements if the changes are anything close to what has been proposed. Prior experience demonstrates that cage construction alone takes 9 to 12 months, and additional time is needed to validate the associated security measures and procedures and train personnel. The abbreviated implementation period reflects a lack of appreciation of the expansive scope of the new proposal and the practical consequences for an operating business entity. DEA should amend the implementation period to reflect more accurately the time it would take to institute the proposed security requirements, providing at least 12 months for current registrants.

#### **IV. Additional Legal Considerations**

The Controlled Substances Act sets forth very specific procedural and substantive requirements that must be met in order for DEA to control a drug or other substance and place it in any schedule.<sup>28</sup> These requirements apply in full to any proposal to reclassify a listed chemical as a schedule III, IV, or V controlled substance. Among other things, DEA would have to make certain findings and provide an opportunity for a hearing to

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<sup>27</sup> *Id.*

<sup>28</sup> 21 U.S.C. §§ 811 & 812(b).

support the scheduling action.<sup>29</sup> Even if DEA were to satisfy these requirements, it could not schedule over-the-counter products containing pseudoephedrine, ephedrine, and phenylpropanolamine as controlled substances. The Controlled Substances Act specifically requires DEA to exclude non-narcotic substances such as pseudoephedrine, ephedrine, and phenylpropanolamine from a schedule if they may be sold lawfully over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>30</sup>

DEA's proposed rule goes part way toward scheduling pseudoephedrine, ephedrine, and phenylpropanolamine as controlled substances by imposing on such chemicals the security requirements for schedule III through V controlled substances. The proposal, of course, does not formally propose the scheduling of these chemicals, but DEA has no authority to accomplish indirectly and by effect what it may not accomplish directly. DEA therefore must tread carefully to avoid in effect reclassifying these listed chemicals as controlled substances without following the requirements of the Controlled Substances Act and without taking steps to exempt lawful OTC products.

Should it proceed with its proposal, DEA should thus clarify that it is not rescheduling these substances. DEA should explicitly state that although it is instituting security controls for pseudoephedrine, ephedrine, and phenylpropanolamine that parallel those required for schedule III through IV controlled substances, it is not rescheduling those chemicals and is not extending any other provision applicable to schedule III through V

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<sup>29</sup> 21 U.S.C. § 811(a).

<sup>30</sup> 21 U.S.C. § 811(g)(1).

controlled substances, such as the regulations governing disposal,<sup>31</sup> to these list I chemicals. Additionally, if DEA proceeds with this rulemaking, DEA can help avoid the risk of attempting effectively to reschedule these products by building additional flexibility into the proposed security requirements, which is appropriate not only to ensure DEA does not overstep its statutory bounds but also as a matter of sound public policy.

The need to preserve flexibility in any new security requirements is further reinforced by other aspects of the statutory scheme. The Controlled Substances Act quite noticeably contains only general references to security measures for listed chemicals. The statute instructs DEA to register an applicant to distribute list I chemicals unless it “determines that registration of the applicant is inconsistent with the public interest.”<sup>32</sup> In determining the public interest, DEA is to consider whether the applicant maintains “effective controls against diversion of listed chemicals into other than legitimate channels.”<sup>33</sup> The statute on its face thus does not require any particular security measures, nor does it direct DEA to develop and impose specific security requirements on chemical registrants.

DEA retains a fair amount of discretion under the law to establish rules and regulations that are necessary and appropriate to implement the statute.<sup>34</sup> Nonetheless, the notable absence of specific security requirements in the statute provides an indication of

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<sup>31</sup> 21 C.F.R. § 1307.21.

<sup>32</sup> 21 U.S.C. § 823(h).

<sup>33</sup> 21 U.S.C. § 823(h)(1).


<sup>34</sup> 21 U.S.C. § 871.

congressional intent. In keeping with the basic approach of the statute and this implicit congressional intent, DEA should take care not to impose overly rigid and prescriptive requirements on listed chemicals and should afford manufacturers and distributors flexibility in adopting security controls so long as those controls are effective.

**V. Conclusion**

CHPA and its members recognize the challenges of preventing the theft and diversion of pseudoephedrine, ephedrine, and phenylpropanolamine. Those challenges must be met through a more workable approach for enhancing security than DEA has proposed, and one linked more carefully to the available factual evidence. More work and analysis is required before new requirements are imposed, particularly those as detailed and rigid as DEA has proposed. The case has not been made to impose the new requirements in the proposed rule. If DEA nonetheless proceeds with adoption of a final rule, it is essential that the changes CHPA has outlined here be incorporated. CHPA appreciates the opportunity to comment, and looks forward to continued dialogue and cooperation with the DEA on these important issues.

Respectfully submitted,

  
Michael S. Labson  
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*Counsel to the Consumer  
Healthcare Products Association*