accordance with the procedures found in 14 CFR 39.19.

Related Information

(i) British airworthiness directive 007–06–2003 also addresses the subject of this AD.

Issued in Renton, Washington, on July 21, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1309

[Docket No. DEA–211P]

RIN 1117–AA62

Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropanolamine

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA is proposing to require that manufacturers, distributors, importers, and exporters of pseudoephedrine, ephedrine, and phenylpropanolamine (PPA) implement security procedures to prevent the theft and diversion of these List I chemicals. These chemicals are available in over-the-counter medications and are widely used in the illicit production of methamphetamine and amphetamine. Based on the number of reports and the size of thefts from manufacturers and distributors of these chemicals, DEA is proposing that these companies implement security measures similar to or as effective as those used for schedule III through V controlled substances. These measures will limit the opportunity for theft and diversion of these chemicals. DEA is soliciting the chemical industry for comments to describe alternate security systems that are equal to the existing controlled substances schedule III through V system.

DATES: To allow adequate time for industry to identify alternative security solutions, written comments must be postmarked, and electronic comments must be sent, on or before October 28, 2004.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–211P'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCD. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/CCD, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* web site. DEA will accept electronic comments containing MS Word, WordPerfect, Adobe PDF, or Excel files only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Special Notice

Due to concerns regarding possible harmful side effects, the Food and Drug Administration (FDA) initiated action in November 2000, to remove phenylpropanolamine (PPA) from the market and requested that all drug companies discontinue marketing products containing PPA. As a result, many firms voluntarily discontinued marketing products containing phenylpropanolamine and removed them from the shelves for disposal. Phenylpropanolamine is a List I chemical, which is used in the illicit synthesis of amphetamine. Once products containing phenylpropanolamine are removed from the market, the requirements being proposed in this rule will affect mainly a few veterinary products containing phenylpropanolamine.

Background

DEA's Legal Authority for These Regulations

DEA implements the Controlled Substances Act (21 U.S.C. 801–971), as amended by the Chemical Diversion and Trafficking Act of 1988 (CDTA), the Domestic Chemical Diversion Control Act of 1993 (DCDCA), the Comprehensive Methamphetamine Control Act of 1996 (MCA) and the Methamphetamine Anti-Proliferation Act of 2000 (MAPA) (Title XXXVI of Pub. L. 106–310), among others. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations pursuant to 21 U.S.C. 821 and 871(b). Regulations relating to the control of listed chemicals are found in 21 CFR parts 1309, 1310 and 1313. These regulations are designed to deter the diversion of listed chemicals to the illegal manufacture of controlled substances. Persons authorized to distribute List I chemicals are registered with the Drug Enforcement Administration, when such registration is determined to be consistent with the public interest. Among other factors used in determining the public interest is a registration applicant's maintenance of effective controls against diversion of listed chemicals into other than legitimate channels (21 U.S.C. 823(h)(1)).

Legitimate Uses of Pseudoephedrine, Phenylpropanolamine, and Ephedrine

Pseudoephedrine and ephedrine are chemicals that are widely used in over-the-counter medications. As noted above, phenylpropanolamine, although previously widely available for human consumption, is now being withdrawn from use in over-the-counter drugs and has only a few human and veterinary uses. Pseudoephedrine is a decongestant used for the temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies. Ephedrine is used for the temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma. Each of the products is available in a variety of dosage forms as a single entity or in combination with antihistamines, antitussives, analgesics, expectorants, and/or vitamins.

The majority of the products containing pseudoephedrine or ephedrine purchased by the public are commonly used medications and are easily accessible at pharmacies, grocery stores, convenience stores, and a variety of other retail stores. Most of these products are available to the public without a prescription. A few products containing pseudoephedrine, phenylpropanolamine, or ephedrine require a prescription issued by a practitioner prior to being dispensed to a patient. This proposed regulation will not adversely impact the public's access to these products as it applies solely to manufacturers and wholesalers of the products. Persons unaffected by this rulemaking include retailers, practitioners, and mid-level

practitioners, the vast majority of DEA's more than one million registrants.

Need for Security Controls on Pseudoephedrine, Ephedrine, and Phenylpropanolamine

Each of these chemicals is a List I chemical because they are used to manufacture methamphetamine (otherwise known as ''speed,'' ''ice,'' ''crystal,'' or ''meth'') and, in the case of phenylpropanolamine, amphetamine. Methamphetamine and amphetamine, which are Schedule II controlled substances, are potent central nervous system stimulants and are drug threats in the U.S.

The earliest clandestine methamphetamine laboratories used the chemical phenyl-2-propanone, also known as phenylacetone or P2P, to produce methamphetamine. When P2P was placed into Schedule II as an immediate precursor, traffickers adjusted by switching to production of methamphetamine using other noncontrolled chemicals. Over the past decade, ephedrine and pseudoephedrine have been the chemicals of choice for the illegal production of methamphetamine. Similarly, clandestine laboratories have used phenylpropanolamine in the illegal production of amphetamine. The principal source of supply for these chemicals continues to be over-the-counter medications. As controls on the sale of over-the-counter products have become more effective, DEA has noted an increase in the number of thefts of the products from distributors and manufacturers. Almost all of the reports of List I chemical thefts in the past few years have involved pseudoephedrine, ephedrine, or phenylpropanolamine.

Illegal Manufacture of Methamphetamine and Amphetamine

Until recent years, most illegal methamphetamine produced in the U.S. was manufactured in large illegal laboratories in California. Large-scale methamphetamine production is still concentrated in California, but smaller scale clandestine methamphetamine laboratories have become common throughout the western and midwestern U.S. and have begun moving into the southeast as well. Further, DEA has encountered instances in which amphetamine is being sold on the street as methamphetamine, as well as instances in which amphetamine/methamphetamine mixtures are being sold. Since 1994, when DEA seized 224 clandestine methamphetamine laboratories, the number of clandestine laboratory seizures has increased dramatically. In 2000, DEA and state and local agencies reported 7,267 clandestine laboratory seizures. In 2001, DEA and state and local agencies reported 8,901 clandestine drug laboratory seizures, 97 percent of which were producing methamphetamine. Reported seizures increased again in 2002 to 9,612, with 97 percent producing methamphetamine. Since not all state, local, and federal agencies that seize clandestine laboratories report seizures to DEA, the total number of clandestine laboratories seized is higher than the numbers reported here.

Although California has the highest number of clandestine drug laboratory seizures (1,168) and almost all of the large-scale clandestine laboratories, other states have witnessed the development of substantial clandestine drug laboratory problems. In 2002, 1,049 clandestine drug laboratories were seized in Missouri, 674 in Washington, 481 in Oklahoma, 435 in Arkansas and Tennessee, 400 in Oregon, 394 in Indiana, 391 in Texas, 364 in Iowa, 336 in Illinois and 334 in Kansas. Arizona, Kentucky and Mississippi had over 200 seizures each while Alabama, Florida, Michigan, Minnesota, New Mexico and Utah had more than 100 seizures each in 2002. Most of these clandestine laboratories produce smaller quantities of methamphetamine for personal use and local distribution. As noted earlier, almost all of the clandestine laboratories, whether large or small, use over-the-counter medications as their principal source of supply of precursor material.

The Source of Over-the-Counter Medications for Clandestine Drug Laboratories

Operators of clandestine drug laboratories obtain over-the-counter medications containing pseudoephedrine, ephedrine, and phenylpropanolamine in three ways. First, some rogue manufacturers, distributors, and retailers continue to sell these chemicals to illegal producers. These purchases are often accomplished through multi-tier sales structuring that attempts to insulate the seller of the chemicals from direct contact with the ultimate criminal end-user. In the summer of 2000, Federal agents, working with state and local law enforcement agencies, arrested more than 140 people in eight cities who allegedly were involved in diverting large quantities of these chemicals to clandestine drug laboratories.

DEA has also seen a significant increase in the amount of product that is illegally obtained from Canada. This product is typically used at large clandestine laboratories. DEA believes that as recently implemented Canadian regulations become more effective at curbing the illegal distribution of product from Canada to the United States, there will be greater pressure on other sources of supply. In fact, recent information indicates a possible decrease in chemicals smuggled from Canada, with an increase of suspicious shipments to and through Mexico.

Second, operators of small clandestine laboratories may purchase these drugs from legitimate retail outlets by making small purchases at multiple stores or having a number of people buy small amounts at a single location. The Methamphetamine Anti-Proliferation Act of 2000 (Title XXXVI of Pub. L. 106–310), reduced the threshold for retail transactions involving non-blister pack products from twenty-four grams to nine grams per individual transaction and added a package size requirement of not more than three grams base ingredient per package. For products sold in blister packs, there is no threshold unless the package contains more than three grams of base ingredient or there are more than two dosage units per blister pack. Several large retail chain stores already limit purchases to three packages of these products at any one time. These changes will make it more difficult for illegal methamphetamine producers to obtain their supplies efficiently through over-the-counter purchases.

Third, as the MCA and MAPA have made it more difficult to obtain these chemicals through legitimate channels, and as DEA and state and local agencies have moved against rogue manufacturers and distributors, legitimate manufacturers and distributors have become targets for employee and outsider theft. DEA anticipates that the pressure on rogue manufacturers and distributors and the limits on legitimate sales will cause even more illegal producers to try theft.

Existing Controls on the Sale of These Chemicals

The principal focus of DEA's requirements with respect to these chemicals has been on regulating sales. Manufacturers, distributors, importers, and exporters are required to identify their customers, maintain records of their distributions, and report suspicious proposed transactions. The requirements have emphasized that manufacturers, distributors, importers, and exporters should ''know your customer'' and ensure that all sales of listed chemicals are for legitimate purposes. Little emphasis has been placed on the security of the products while in the possession of

manufacturers, distributors, importers, and exporters. DEA has noted an increase in the reported theft of these products from manufacturers and distributors.

The high street value of these over-the-counter medications makes them an attractive target for thieves. Unlike most items that are stolen, which can be sold on the black market for only a fraction of their retail price, a case of these products (*e.g.*, 144 bottles of 60 count 60-mg pseudoephedrine dosage units) commands a premium on the black market. The wholesale value of a case is between $400 and $500, while the black market price varies between $800 and $5000, depending on the location.

Theft is also attractive because these products are usually stored with other consumer products in warehouses and are sometimes left unattended on loading docks and in freight yards while waiting to be shipped or stored. Although most distributors have security controls for high cost items, such as cameras, they have not usually applied such controls to these products. As a result of the limited security controls placed on these products (*i.e.*, controlled access, employer and employee responsibility to report diversion), an increasing number of thefts are occurring and being reported to DEA.

The Theft Problem

From late 1995 through late 2003, DEA received reports of thefts and losses of more than 1,000 kilograms of bulk ephedrine, pseudoephedrine, and phenylpropanolamine and more than 15 million dosage units or 823 kilograms of these chemical products. (The calculations were based on the smallest dosage unit strength in the absence of the specific information.) The bulk product thefts listed below could produce 2,400 pounds of methamphetamine. The dosage unit thefts could produce about 1,660 pounds. (These estimates are based on theoretical yields. Actual yields depend on the practices and sophistication of a specific clandestine laboratory.) The street value of the methamphetamine that could have been produced from these thefts ranges from $26 million to $122 million.

During the period covered by these reports (late 1995 through late 2003), DEA received very few theft reports that involved other listed chemicals. The nature of the over-the-counter products, their demand and value on the black market, and the absence of effective security controls make them an attractive target for theft.

The lack of understanding of the widespread threat of theft of these products is illustrated by the case of a major distributor with multiple facilities. In 1998, employees at one of the distributor's warehouses stole more than 72,000 dosage units of pseudoephedrine and phenylpropanolamine, some of which were found at a clandestine methamphetamine laboratory. The company responded by installing better security systems at that one warehouse. A second 1998 theft from another of the company's warehouses resulted in a loss of 800,000 dosage units. In 1999, employees at a third warehouse stole more than 500,000 dosage units of pseudoephedrine and phenylpropanolamine, which were found at more than 20 clandestine methamphetamine laboratories and dump sites. In 2000, employees at a fourth company warehouse stole 1,200 dosage units, and at a fifth warehouse, the company discovered and reported eight separate thefts, which totaled almost a million dosage units. In total, this single company lost well over two million dosage units during a three year period. Despite this pattern of theft, the company improved security only after the thefts and only at the warehouses where a theft occurred; there was no apparent effort to proactively establish additional security for the products at other locations operated by the company.

Thefts reported to DEA include, but are not limited to, the following:

Bulk Chemical Thefts

- A manufacturer reported the theft of 90 kilograms (kg) of pseudoephedrine
- An employee stole 12 kg of pseudoephedrine from a manufacturer.
- A manufacturer was robbed of two 25-kg drums of pseudoephedrine stolen, but recovered them. A subsequent inventory check showed a third drum was missing.
- A manufacturer had most of the chemical ingredients needed to make methamphetamine clandestinely (hydriodic acid, red phosphorus, iodine, ephedrine, and pseudoephedrine) stolen from outside a fence. Included in the theft was 4.375 kg of pseudoephedrine.
- A manufacturer had 11.22 kg of pseudoephedrine stolen from a movable cart.
- A distributor had two 25-kg drums of pseudoephedrine stolen from a locked trailer.
- Employees stole 390.91 kg of ephedrine from a manufacturer.
- A manufacturer lost 23 kg of pseudoephedrine.
- A manufacturer lost 55.6 kg of pseudoephedrine during the manufacturing process.
- A manufacturer had eight 55 pound drums of pseudoephedrine (200 kg) stolen from a storage cage which was missing a lock.
- An importer had 70.4 kg stolen from an unlocked quarantine cage.
- A manufacturer had an unexplained loss of 17.87 kg of pseudoephedrine.
- An analytical laboratory had 90 kg of ephedrine stolen during a burglary.

Dosage Unit Thefts

- An employee or employees stole 4,201,112 pseudoephedrine dosage units from a manufacturer.
- A distributor had 150,400 pseudoephedrine 30 mg dosage units and phenylpropanolamine 24.3 mg dosage units stolen.
- A distributor reported the loss of 674,800 pseudoephedrine dosage units in seven thefts from an open area of the warehouse with unrestricted access for employees. The same location reported another theft of 294,900 dosage units from outside a cage.
- A distributor reported the loss of 800,000 pseudoephedrine dosage units due to employee theft.
- A distributor lost 418,224 dosage units of ephedrine and pseudoephedrine in an armed robbery.
- A distributor had 85,000 dosage units of pseudoephedrine and ephedrine stolen.
- An employee stole more than 1,200 pseudoephedrine dosage units.
- A mail order pharmacy had more than 66,000 pseudoephedrine dosage units stolen after they were dropped off by a delivery truck.
- A manufacturing relabeler reported the loss of 83,333 ephedrine dosage units.
- A distributor had a trailer stolen containing more than 22,080 dosage units of pseudoephedrine.
- A hospital lost more than 756,600 pseudoephedrine 60 mg dosage units from an open warehouse, where access was unrestricted.
- A manufacturer had more than 266,669 ephedrine 180 mg dosage units stolen from its waste stock.

A distributor found major shortages in 27 of 34 lots examined; more than 1,578,628 pseudoephedrine and ephedrine dosage units were missing.

- A distributor had a trailer stolen from a residence; the trailer contained more than 96,768 dosage units, some of which were later found at a clandestine laboratory dump site.
- A distributor had a trailer stolen containing 9,216 dosage units of pseudoephedrine.

- An employee stole 8,000 dosage units of pseudoephedrine from a distributor.
- An employee stole 51,100 pseudoephedrine 60 mg dosage units from manufacturer.
- A distributor lost 311,040 pseudoephedrine 60 mg dosage units during a burglary.
- A locked trailer load of over the counter products containing 1,833,504 dosage units of pseudoephedrine was stolen from a distributor.
- A manufacturer had an unexplained loss of 3,288 30 mg dosage units of pseudoephedrine.
- During a routine inventory 40,000 60 mg dosage units of pseudoephedrine were found to be missing from a holding area in a distributor's warehouse. Employee pilferage was suspected.
- A distributor discovered the loss of 119,800 30 mg dosage units of pseudoephedrine from its off site storage warehouse.
- An employee of a manufacturer stole approximately 75,000 dosage units of pseudoephedrine and conspired with others to manufacture methamphetamine. The employee was subsequently arrested.
- An analytical laboratory lost 76,968 120 mg dosage units of pseudoephedrine from a locked in process storage room.
- A distributor lost 7,200 120 mg dosage units of pseudoephedrine.

Impact of Methamphetamine Abuse

As the dramatic increase in the number of clandestine laboratory seizures indicates, methamphetamine abuse is a serious problem. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), Drug Abuse Warning Network, in 2002, methamphetamine was mentioned in almost 18,000 emergency room visits; from 1994 through 2002, there were about 130,000 emergency room visits where methamphetamine was mentioned. (Drugs are often used in combination; it is not possible to determine which drug led to the emergency room visit, if any; in some cases, a patient may have sought treatment unrelated to the drug use.) In 1993, amphetamine treatment admission rates were high in a few Western States—California, Oregon, and Nevada. By 1999, SAMHSA reported that high amphetamine treatment admission rates were seen in most states west of the Mississippi. Amphetamine treatment admission rates increased between 1993 and 1999 by 250 percent or more in 14 states and by 100 to 249 percent in another 10 states. SAMHSA data from 23 metropolitan areas indicate that methamphetamine was involved in more than 500 deaths in 2001.

The surge in methamphetamine abuse has caused serious law enforcement and environmental problems, particularly in rural communities. Rural areas are frequently the site of clandestine laboratories because the manufacturing process produces distinctive odors and can be identified if there are close neighbors. The district attorney of Snohomish County in western Washington reported that two thirds of all crimes in the county are tied to methamphetamine. The number of lab seizures in the county exceeded the number of seizures in New England, New York, and Pennsylvania combined.

Besides causing crime as people steal ingredients to make methamphetamine and steal to support their addiction, the clandestine laboratories often leave serious pollution behind. In 2002, Washington state alone had more than 2,000 sites that required immediate clean-up. A laboratory can produce 6 to 10 pounds of hazardous waste for every pound of methamphetamine produced. In 2003, DEA funded clean-ups of approximately 8,600 clandestine laboratories and estimates that states have funded an equal number of clean-ups. California is reported to have spent about $10 million in 2000 for clean-ups. The Federal and State clean-ups are generally limited to removing chemicals that could be reused; they do not address water and soil pollution that remain. Owners of the property are responsible for completing the clean up of contaminated water and soil, but if the owner cannot pay the cost, local governments bear the burden or the contamination remains.

DEA's Proposal

DEA initially required manufacturers, distributors, importers, and exporters of List I chemicals to implement minimal physical security measures, such as tamper proof storage containers. DEA depended on the individual firms to adequately safeguard the materials in their possession. However, this approach has not been successful even though the affected industry is aware of the problems associated with the diversion of List I chemicals and their use to illegally manufacture methamphetamine. Due to the reported thefts of pseudoephedrine, ephedrine, and phenylpropanolamine and the significant increase in the amount of illegal methamphetamine produced from these products, DEA is proposing that a medium level of security be placed on the areas where pseudoephedrine, ephedrine, and phenylpropanolamine are stored. The proposed regulations allow for a number of security options that may be used for the storage of these products. Therefore, small businesses with minimal inventory will have low cost options available that comply with the proposed regulations. In addition, many of the affected entities with large inventories of pseudoephedrine, ephedrine, and phenylpropanolamine already have secure storage facilities that comply with the requirements.

DEA is proposing that manufacturers, distributors, importers, and exporters of pseudoephedrine, ephedrine, and phenylpropanolamine implement security procedures that are similar to or as effective as those now used by registrants handling Schedule III through V controlled substances. These procedures may include the storage of the substances in a secure safe or steel cabinet, cage, or room and installation of a monitored alarm system linked to a central location or procedures that generally provide the same level of protection. Safes or steel cabinets would need alarm systems only if more than a total of one (1) kilogram of pseudoephedrine, ephedrine, and phenylpropanolamine, combined, were stored at any one time. In evaluating their overall security system, chemical registrants should consider the factors which DEA considers relevant in evaluating overall security requirements for chemical applicants and registrants. These factors are specified in 21 CFR 1309.71(b)(1) through (8):

(1) The type, form, and quantity of List I chemicals handled;

(2) The location of the premises and the relationship such location bears on the security needs;

(3) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) The availability of electronic detection and alarm systems;

(5) The extent of unsupervised public access to the facility;

(6) The adequacy of supervision over employees having access to List I chemicals;

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored;

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

In light of the need for increased security chemical registrants may also wish to consider the factors which DEA considers relevant in evaluating overall security requirements for controlled

substances applicants and registrants. These factors are specified in 21 CFR 1301.71(b)(1) through (14):

(1) The type of activity conducted (*e.g.*, processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances (regulated chemicals) handled (*e.g.*, bulk liquids or dosage units, usable powders or nonusuable powders);

(3) The quantity of controlled substances (regulated chemicals) handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage systems (*e.g.* automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled substances (regulated chemicals) in its operations.

DEA believes that schedule III through V controlled substances security requirements implemented correctly by chemical handlers would be one responsible approach in an effort to deter theft and diversion of regulated chemicals. Keeping pseudoephedrine, ephedrine, and phenylpropanolamine products in such secure areas limits the opportunity for theft. Controlled limited access to such areas discourages employee theft because it makes the identity of the thief easier to determine. However, DEA is soliciting and will consider recommendations regarding alternative means to achieve the same level of security including industry-sponsored security systems and activities, recognizing that in certain circumstances the implementation and use of schedule III through V controlled substances security may pose significant challenges. Therefore, in an effort to accommodate the industry's concerns about implementing this type of security system, DEA requests, invites, and solicits the chemical industry to provide specific efficient and economically acceptable alternatives to the system now required for controlled substances registrants.

Cost of Proposed Security Measures

The ultimate costs of the proposed security will depend on the types of economically acceptable alternatives to the system now required for controlled substance registrants that the chemical industry can provide to DEA. The costs of an alternative system, if adopted, may be significantly less than those discussed in the ensuing paragraphs.

DEA investigated the costs of security systems currently used by controlled substances registrants with emphasis that the economic impact would not place an unreasonable burden on small distributors. These systems allow for a number of security options for the storage of ephedrine, pseudoephedrine, and phenylpropanolamine, including a safe or steel cabinet, a cage, and a separate room within the facility. To develop unit cost estimates, DEA contacted several firms that supply and install various types of security containers and alarm systems to determine the range of costs for each system. DEA determined that a cage is the least expensive storage option if a specific structure is selected. Safes and steel cabinets that meet DEA security requirements would be more costly than a cage. Setting aside a room may not be a feasible option for warehouse operations; many distributors already use cages to store items that are likely to be targets of theft.

As of November 3, 2003, 3,232 distributors were registered to handle at least one of the three drugs; of these, 1,228 were registered to handle all three. Most registrants handle pseudoephedrine (3,092). Of the 3,232 handlers registered with DEA, five are retailers who will not be subject to the new security requirements and are therefore not part of the affected population. Further, DEA determined that 96 of 206 registered importers and exporters do not actually conduct import and export transactions of these drugs. However, to account for constant fluctuations in the registrant population, DEA estimated that this rulemaking would affect approximately 3,100 DEA registrants, including wholesale distributors, manufacturers, and importer/exporters.

As noted above, according to security firms, a cage is likely to be the least expensive option for a facility that stores materials in a warehouse, costing between $2,400 and $3,670 (in 2004 dollars) to purchase and install. Cages vary in cost based on their size. DEA assumed that most distributors are not storing large quantities of these products at any one time and that an 800 cubic feet cage would be sufficient; such a cage could hold at least 5 million dosage units. The costs of a cage were depreciated over 15 years, hence the annual cost of the cage would be between $265 and $403.

An alarm system would cost between $2,100 and $4,190 to purchase and install. Although an alarm system is likely to function for at least 15 years, the analysis depreciated the costs over five years; the annual cost of the alarm system would be between $511 and $1,022. Annual costs for alarm system monitoring and maintenance would be about $1,150. The total annual cost of the equipment per distributor facility (present value over 15 years) would range from $5,700 to $ 9,000. The annualized cost for the equipment and ongoing costs is approximately $1,900 to $2,600 for each distributor.

DEA assumed that the manufacturers and exporters would already have secure storage systems and alarms and would only need to add an annual alarm monitoring system. Because these registrants were assumed to have a much larger alarm system than distributors have, the annual cost for monitoring the system is higher, about $3,100.

The total annualized cost for all affected entities (the approximately 3,100 manufacturers, distributors, importers, and exporters) is between $6.8 million and $8.7 million. The total cost of meeting the security requirements over a 15-year time frame for all affected manufacturers, distributors, importers, and exporters of pseudoephedrine, ephedrine, and phenylpropanolamine is estimated to be between $62 million and $80 million. DEA has been cautious in its approach to estimating the actual costs of implementing the proposed security requirements. Many of the affected entities may already have monitored alarm systems and/or secure storage areas in their facilities to secure other types of products such as small electronic devices, tobacco, or controlled substances. Therefore, the

existing systems could be used to comply with these proposed regulations and the actual additional costs to implement the security requirements will be less than the estimates provided here. Manufacturers, distributors, importers, and exporters are asked to comment on the security measures that are currently utilized in their facilities.

Benefits of the Proposed Rule

If the thefts reported to DEA from 1995 to 2003 constituted all relevant thefts, and if the pattern of thefts were to continue for the next 15 years, assuming no increase in thefts or in the street value of clandestinely produced methamphetamine, the total value of the methamphetamine that could be produced from stolen chemicals over that time would range from $66 million to $307 million. These drugs impose substantial costs on the U.S. economy. As noted above, methamphetamine was mentioned in almost 18,000 emergency room visits in 2002. The cost of these visits range from $8.5 million to $29 million. (Estimates are based on a 1996 national average cost of emergency room visits of $383 reported in the New England Journal of Medicine and a 1997estimate from the Centers for Disease Control of $1,324 for the average cost of emergency room visit for asthma, adjusted to 2004 dollars). In addition, there are costs associated with addiction treatment, law enforcement, and clean up of lab sites. Each of these costs individually is likely to be higher than the total annual costs of security measures. Finally, some of the more than 500 deaths a year associated with methamphetamine could be averted if diversion of these over-the-counter drugs could be curtailed.

Effective Date for Installation of the Security Measures

If finalized, manufacturers, distributors, importers and exporters will have 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**; therefore affected entities will have a total of 120 days to implement the security requirements. If a timely and good faith effort has been made to implement the requirements, and it is determined that an affected entity will be unable to meet the required deadline, then the local DEA office must be notified to make alternate arrangements in the interim.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)). Although the proposed rule will impact a substantial number of small entities (about 2,800 distributors, most of them small businesses), it will not have a significant adverse financial impact on them.

In the North American Industry Classification System (NAICS) (the successor to the Standard Industrial Classification System (SIC code)), the affected manufacturers are most likely to be classified as part of the pharmaceutical industry while importers and exporters are likely to be classified as part of the ''all other inorganic chemical manufacturing'' industry. Distributors are most likely to be captured as part of either the drug and druggists' sundries wholesale sector or the tobacco and tobacco product wholesale sector. DEA further assumes that all manufacturers, exporters, and importers are relatively large in size, but that all of the affected distributors are small businesses, based on the small business size standards provided by the Small Business Administration.

The annual costs for distributors ($1,900–$2,600) represent 0.1 percent to 0.2 percent of the average annual sales of the smallest class of distributors (one to four employees) in the drug and druggist sundries sector (annual sales $1.3 million) and tobacco and tobacco products sector (annual sales $1.9 million) sectors and less than 0.05 percent of average annual sales for the next class (five to nine employees) (annual sales of $4.7 million and $6.3 million respectively). Sales data are from the 1997 Economic Census and, therefore, are likely to be understated.

Even if costs are considered as one-time, non-amortized values, they represent no more than 0.7 percent of the smallest distributor's 1997 sales. Although the Small Business Administration provides no definitive guidance on how to define a significant economic impact, one percent of sales or revenues is a commonly used standard to define the level at which costs may impose an adverse economic impact. The costs of this rule do not approach that level and are likely to be considerably less than the estimated costs because most distributors already have some security systems to protect other goods.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). It has been determined that this rule is a significant rulemaking action, and, therefore, this rulemaking has been reviewed by the Office of Management and Budget. As discussed above, DEA has conducted an economic analysis of the security requirements proposed in this rulemaking and does not believe that these proposed security requirements would have a significant economic impact. DEA believes that the security requirements proposed here are necessitated by the value of pseudoephedrine, ephedrine and phenylpropanolamine on the black market, and the value of amphetamine and methamphetamine on the streets. The benefits of preventing the diversion of these drugs far outweigh the costs.

DEA is requesting manufacturers, distributors, importers, and exporters of List I chemicals to comment on the specific types of security measures that are currently utilized in their facilities and the specific costs that will be necessary to adopt the proposed new security requirements.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $113,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a

major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and II chemicals, Security measures.

For the reasons set out above, 21 CFR part 1309 is proposed to be amended as follows:

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS, AND EXPORTERS OF LIST I CHEMICALS

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

§ 1309.24 [Amended]

2. § 1309.24(k) is proposed to be amended by removing the phrase ''§§ 1309.71–1309.73'' and replacing it with the phrase ''§§ 1309.71–1309.74'.

3. Section 1309.74 is proposed to be added to read as follows:

§ 1309.74 Security requirements for pseudoephedrine, ephedrine, and phenylpropanolamine.

(a) Manufacturers, distributors, importers, and exporters must store pseudoephedrine, ephedrine, and phenylpropanolamine raw materials, bulk materials awaiting further processing, and finished products in a secure storage area. The secure area may be a safe or steel cabinet, as specified in paragraph (c) of this section; a secure room that meets the requirements of paragraph (d) of this section; a cage that meets the requirements of paragraph (e) of this section; or other areas approved by the Administrator (paragraphs (f) and (g) of this section). Secure rooms, cages, and other areas approved by the Administrator must have an alarm system that meets the requirements of paragraph (b) of this section. A safe or steel cabinet must have an alarm system if a total of 1 kilogram or more, combined, of pseudoephedrine, ephedrine, and phenylpropanolamine materials are stored at any one time.

(b) The secure storage area must be equipped with an alarm system that, upon attempted unauthorized entry, transmits a signal directly to a central protection company, a local or State police agency that has a legal duty to respond, a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(c) Where small quantities (less than one (1.0) kilogram of pseudoephedrine, ephedrine or phenylpropanolamine, combined) permit, pseudoephedrine, ephedrine, and phenylpropanolamine may be stored in a safe or steel cabinet that meets the following requirements:

(1) The safe or steel cabinet must conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; and

(2) If the safe or cabinet weighs less than 750 pounds, it must be bolted or cemented to the floor or wall in such a way that it cannot be readily removed.

(d) Pseudoephedrine, ephedrine, and phenylpropanolamine may be stored in a secure room with perimeter security that limits access during working hours and provides security after working hours. The secure room must be equipped with self-closing, self-locking doors constructed of substantial material. A door that is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Where hinges are mounted on the outside, the hinges must be sealed, welded, or otherwise constructed to inhibit removal. Locking devices for such doors must be of either the multiple-position combination or key lock type and must comply with one of the following:

(1) In the case of key locks, the lock must require key control that restricts access to a limited number of employees.

(2) In the case of combination locks, the combination must be limited to a minimum number of employees and must be changed upon termination of employment of an employee having knowledge of the combination.

(e) Pseudoephedrine, ephedrine, and phenylpropanolamine may be stored in a cage, located within a building on the premises, meeting the following specifications:

(1) The cage walls must be constructed of not less than No.10 gauge steel fabric mounted on steel posts. The posts must be:

(i) At least one inch in diameter;

(ii) Set in concrete or installed with lag bolts that are pinned or brazed; and

(iii) Placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches.

(2) The cage must have a mesh construction with openings of not more than two and one-half inches across the square.

(3) The cage must have a ceiling constructed of the same material or, in the alternative, a cage must be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.

(4) The cage must be equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and which conforms to all the requirements of paragraph (d) of this section in all other respects.

(f) Pseudoephedrine, ephedrine, and phenylpropanolamine may be stored in an enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage.

(g) Pseudoephedrine, ephedrine, and phenylpropanolamine may be stored in such other secure storage areas as may be approved by the Administrator after considering the factors listed in § 1309.71(b)(1) through (8).

(h) Nonregulated chemicals and other materials may be stored with pseudoephedrine, ephedrine, and phenylpropanolamine in any of the secure storage areas required by this section, if permission for the storage of non-controlled items is obtained in advance, in writing, from the DEA Special Agent in Charge for the area in which the storage area is located. Any permission granted must be based on the Special Agent in Charge's written determination that such non-segregated storage does not diminish the effectiveness of security for pseudoephedrine, ephedrine, and phenylpropanolamine.

(i) The pseudoephedrine, ephedrine, and phenylpropanolamine storage areas must be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through pseudoephedrine, ephedrine, and phenylpropanolamine storage areas, the registrant must provide for adequate observation of the area by an employee specifically authorized in writing.

Dated: July 23, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

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