Research Assistant A's experience is on the cutting edge of a breakthrough in the field and his/her work history is distinguished by frequent praise and recognition in writing and through awards. Research Assistant B (the nonimmigrant) has a respectable work history but has not conducted research which has been internationally recognized. Employer pays Research Assistant A $10,000 per year more than Research Assistant B in recognition of his/her unparalleled expertise and accomplishments. The employer now wants to hire a third Research Assistant on an H–1B visa to participate in the work.

The differential between the salary paid Research Assistant A (the U.S. worker) and Research Assistant B (an H–1B nonimmigrant) is acceptable because it is based upon the specialized knowledge, expertise and experience of Research Assistant A, demonstrated in writing. The employer is not required to pay Research Assistant B the same wage rate as that paid Research Assistant A, even though they may have the same job titles. The actual wage required for the third Research Assistant, to be hired on an H–1B visa, would be the wage paid to Research Assistant B unless he/she has internationally recognized expertise similar to that of Research Assistant A. As set out in § _____.731(1)(A) the employer must have and document the system used in determining the actual wage of H–1B nonimmigrants. The explanation of the system must be such that a third party may use the system to arrive at the actual wage paid the H–1B nonimmigrant.

(4) Employer located in City X seeks experienced mechanical engineers. In City X, the prevailing wage for such engineers is $49,500 annually. In setting the salaries of U.S. workers, employer pays its nonsupervisory mechanical engineers with 5 to 10 years of experience between $50,000 and $75,000 per year, using defined pay scale ''steps'' tied to experience. Employer hires engineers A, B, and C, who each have five years of experience and similar qualifications and will perform substantially the same nonsupervisory job duties. Engineer A is from Japan, where he/she earns the equivalent of $80,000 per year. Engineer B is from France and had been earning the equivalent of $50,000 per year. Engineer C is from India and had been earning the equivalent of $20,000 per year. Employer pays Engineer A $80,000 per year, Engineer B $50,000, and Engineer C $20,000 as the employer has had a long-established system of maintaining the home-country pay levels of temporary foreign workers.

The INA requires that the employer pay the H–1B nonimmigrant at least the actual wage or the prevailing wage, whichever is greater, but there is no prohibition against paying an H–1B nonimmigrant a greater wage. Therefore, Engineer A may lawfully be paid the $80,000 per year. Engineer B's salary of $50,000 is acceptable, since this is the employer's actual wage for an engineer with Engineer B's experience and duties. Engineer C's salary, however, at a rate of $20,000 per year, is unacceptable under the law, even given the employer's ''long-established 'home country' system,'' since $20,000 would be below both the actual wage and the prevailing wage. The latter situation is an example of an illegitimate business factor, *i.e.,* a system to maintain salary parity with peers in the country of origin, which yields a wage below the required wage levels.

11. In § _____.840, paragraph (c) is republished as follows:

§ _____.840 Decision and order of administrative law judge.

* * * * *

(c) In the event that the Administrator's determination(s) of wage violation(s) and computation of back wages are based upon a wage determination obtained by the Administrator from ETA during the investigation (pursuant to § _____.731(d) of this part), and the administrative law judge determines that the Administrator's request was not warranted (under the standards in § _____.731(d) of this part), the administrative law judge shall remand the matter to the Administrator for further proceedings on the issue(s) of the existence of wage violation(s) and/or the amount(s) of back waged owed. If there is no such determination and remand by the administrative law judge, the administrative law judge shall accept such wage determination as accurate. Such wage determination is one made by ETA, from which the employer did not file a timely complaint through the Employment Service complaint system or from which the employer has appealed through the ES complaint system and a final decision therein has been issued. See § _____.731 of this part; see also 20 CFR 658.420 through 658.426. Under no circumstances shall the administrative law judge determine the validity of the wage determination or require source data obtained in confidence by ETA or the SESA, or the names of establishments contacted by ETA or the SESA, to be submitted into evidence or otherwise disclosed.

* * * * *

[FR Doc. 95–26921 Filed 10–30–95; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310, and 1313

[DEA–138P]

RIN 1117–AA32

Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to remove the exemption for certain products containing pseudoephedrine (which are lawfully marketed under the Federal Food, Drug, and Cosmetic Act) from the chemical control provisions of the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act. Due to the large scale utilization of over-the-counter (OTC) pseudoephedrine products for the clandestine manufacture of controlled substances, the DEA has determined that certain products should be subject to recordkeeping, reporting, registration and notification requirements of the CSA to prevent their diversion. Such products include OTC tablets, capsules and powder packets containing pseudoephedrine alone or in combination with antihistamines, quaifenesin or dextromethorphan. This action also proposes that the threshold for pseudoephedrine be reduced to 24.0 grams pseudoephedrine base. Such a threshold is sufficient to permit the purchase of up to a 120 day supply of pseudoephedrine without the application of regulatory requirements.

To further ensure the availability of pseudoephedrine products to legitimate consumers at the retail level, this action also proposes to waive the registration requirement for retail distributors of regulated pseudoephedrine products.

DATES: Written comments and objections must be received by January 2, 1996.

FOR FURTHER INFORMATION CONTACT: Howard McClain Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537. Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

The Chemical Diversion and Trafficking Act (PL 100–690) (CDTA)

amended the Controlled Substances Act and the Controlled Substances Import and Export Act, and was passed by Congress to control the diversion of certain chemicals (herein referred to as listed chemicals) that are necessary for the illicit production of controlled substances. The CDTA and its implementing regulations as set forth in Title 21, Code of Federal Regulations (21 CFR), parts 1310 and 1313, established a system of recordkeeping and reporting requirements through which DEA and the chemical industry could identify persons seeking to divert listed chemicals for the manufacture of illicit drugs. While bulk ephedrine and pseudoephedrine were regulated under the CDTA, ephedrine and pseudoephedrine products which are lawfully marketed or distributed under the Federal Food, Drug, and Cosmetic Act (FD&C Act), were originally exempt from CDTA regulations.

Since 1989, ephedrine has been the primary precursor used in the clandestine synthesis of methamphetamine in the United States. Clandestine laboratory operators have exploited the lack of controls on OTC ephedrine products (such as tablets/capsules) to purchase millions of dosage units for the synthesis of methamphetamine and methcathinone.

The Domestic Chemical Diversion Control Act (DCDCA) of 1993 (Public Law 103–200) became effective on April 16, 1994. This Act further amended the Controlled Substances Act and the Controlled Substances Import and Export Act and removed the exemption for those transactions involving products which are marketed or distributed lawfully in the U.S. under the Federal Food, Drug, and Cosmetic Act, if these products contain ephedrine (or its salts, optical isomers, or salts of optical isomers) as the only active medicinal ingredient or contain ephedrine in combination with therapeutically insignificant quantities of another active medicinal ingredient. Thus single entity ephedrine products became subject to reporting, recordkeeping and notification requirements of the CSA. The DCDCA, however, did not remove the exemption provided for pseudoephedrine OTC products, since the known illicit use of pseudoephedrine was relatively infrequent when the DCDCA was enacted.

The DCDCA also provided the Attorney General with the authority to remove the exemption for any drug product containing a listed chemical upon a determination that the drug product is being diverted for use in the illicit production of a controlled substance. In addition, the DCDCA imposed registration requirements for List I chemical handlers.

The CDTA established a system of thresholds for each listed chemical to determine which transactions would be subject to regulatory controls. Reporting, recordkeeping and notification requirements apply to all regulated transactions which meet or exceed these threshold amounts of a listed chemical. The threshold for ephedrine was originally established as 1.0 kilogram for domestic, import and export transactions. The threshold of 1.0 kilogram of ephedrine base is equivalent to greater than 48,800 ephedrine 25 mg dosage units. Even though the dosage form exemption was eliminated by the DCDCA, a 1.0 kilogram threshold was not adequate to prevent the significant diversion of ephedrine to clandestine laboratories in the United States.

Given evidence of the large-scale diversion of ephedrine from various types of outlets and the public health threat imposed by the diversion of these products, the DEA determined that additional action was needed to prevent further diversion. Effective November 10, 1994 (59 FR 51365) the DEA eliminated the threshold for ephedrine. Subsequently, all regulated transactions of ephedrine became subject to reporting, recordkeeping and notification requirements of the CSA regardless of size.

In response to regulatory and other actions taken against single-entity ephedrine products, clandestine laboratory operators have again attempted to circumvent CSA chemical controls in an effort to obtain precursor material. The search for unregulated sources of precursor material has led to the diversion and illicit utilization of OTC ephedrine combination products and OTC pseudoephedrine products. The DEA is currently reviewing the regulatory options which address the diversion of OTC ephedrine combination products. This issue will be addressed in the near future.

Pseudoephedrine and ephedrine are related as diastereomers. Because of this structural relationship, pseudoephedrine can serve as a direct substitute for ephedrine in the synthesis of methamphetamine. Clandestine laboratory operators are exploiting the lack of regulatory controls on OTC pseudoephedrine products by obtaining pseudoephedrine for use as precursor material for the synthesis of methamphetamine.

Due to the significant increase in the utilization of pseudoephedrine products for the illicit manufacture of these controlled substances, the DEA Deputy Administrator has determined that some of these products should be subject to recordkeeping, reporting, registration and notification requirements of the Controlled Substances Act and the Controlled Substances Import and Export Act, in order to prevent their diversion. This action proposes to remove the exemption for certain OTC products containing pseudoephedrine. These pseudoephedrine products shall therefore be subject to regulatory provisions of the CSA.

Removal of Exemption

21 U.S.C. 814(a) provides that the Attorney General may remove from exemption under 21 U.S.C. 802(39)(A)(iv) any drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. 21 U.S.C. 814(b) further provides that in removing the exemption for a drug or group of drugs, the Attorney General shall consider (1) the scope, duration, and significance of the diversion, (2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and (3) whether the listed chemical can be readily recovered from the drug or group of drugs. A summary analysis of these factors follows.

Methamphetamine is the most prevalent controlled substance clandestinely synthesized in the United States. Between January 1, 1994 and September 15, 1995 the DEA has been involved in the domestic seizure of 453 methamphetamine laboratories. Ephedrine and/or pseudoephedrine were utilized as the precursor material at approximately 85 percent of these laboratories.

Evidence of the illicit utilization of pseudoephedrine in clandestine laboratories is increasing. The identification of OTC pseudoephedrine products at clandestine methamphetamine laboratories increased dramatically in 1995. Pseudoephedrine was utilized in at least 11 percent of the laboratories seized in 1994 and 22 percent in 1995. The DEA and local law enforcement have intercepted and seized millions of pseudoephedrine dosage units from mail order shipments destined for individuals for subsequent use in the illicit manufacture of methamphetamine.

Pseudoephedrine is available in a variety of dosage forms either as single entity products or in combination with one or more other active medicinal ingredients. While the majority of OTC

pseudoephedrine products currently used for the illicit production of methamphetamine are single entity products, some combination products have been identified at clandestine laboratories. The DEA has reviewed the various pseudoephedrine dosage forms and available combinations of ingredients. Some of these products are formulated in such a way that the product itself can be used in the illicit production of methamphetamine; others are formulated in such a way that pseudoephedrine can be readily recovered from the product; and some of these products are formulated in such a way that the manufacture of methamphetamine is impeded. Based on this analysis, the DEA has determined that OTC solid dosage form products (i.e. tablets, capsules and powder packets) lawfully marketed under the Federal Food, Drug, and Cosmetic Act and which contain pseudoephedrine in combination with acetaminophen, aspirin or ibuprofen are formulated in such a way that pseudoephedrine cannot be readily recovered and these products are not easily used as precursors for the illicit production of methamphetamine. In addition, the DEA has determined that OTC liquids, syrups and soft gelatin capsules, which are lawfully marketed under the Food, Drug, and Cosmetic Act and which contain pseudoephedrine either as the sole active ingredient or in combination with other active ingredients, are formulated in such a way that the pseudoephedrine cannot be readily recovered and the products cannot be easily used in the illicit production of methamphetamine.

Thus the DEA is proposing to remove the exemption under 21 CFR 1310.01(f)(1)(iv) for OTC solid dosage form pseudoephedrine products (i.e. tablets, capsules and powder packets) lawfully marketed under the Food, Drug, and Cosmetic Act, which do not contain therapeutically significant quantities of acetaminophen, aspirin or ibuprofen. These products, which include tablets, capsules and powder packets containing pseudoephedrine as the sole active ingredient or in combination with one or more active indgredients such as antihistamines, guaifenesin or dextromethorphan, will be subject to the regulatory requirements of the CSA.

For purposes of this paragraph, the term ''therapeutically significant quantities'' shall apply if the product formulation (i.e. the qualitative and quantitative composition of active ingredients within the product) is listed in current editions of the American Pharmaceutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.). For drug products having a formulation not found in the above compendiums, the DEA Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph.

The exemption provided under 21 CFR 1310.01(f)(1)(iv) will remain for liquids, syrups, and soft gelatin capsules containing pseudoephedrine and any type of solid dosage form product which contains pseudoephedrine in combination with therapeutically significant quantities of either acetaminophen, aspirin or ibuprofen provided that the product is lawfully marketed under the Food, Drug, and Cosmetic Act. In addition, the proposed regulations allow pseudoephedrine prescription products, regardless of the product formulation, to remain exempt from the proposed regulations, given existing distribution and dispensing requirements already imposed under the Federal Food, Drug and Cosmetic Act.

Pursuant to 21 U.S.C. 814(c), the DEA has considered the evidence of diversion of the above listed pseudoephedrine products, the pattern of diversion of ephedrine products, including combination products and other relevant data, and has determined that the affected group of pseudoephedrine products is limited to that necessary to prevent the diversion of pseudoephedrine products to illicit methamphetamine laboratories.

Revision of Threshold

The current threshold for pseudoephedrine is 1.0 kilogram for domestic, import and export transactions. Even if the exemption for certain OTC pseudoephedrine products is eliminated, a 1.0 kilogram threshold is not adequate to prevent the significant diversion of these pseudoephedrine products to clandestine laboratories. The threshold of 1.0 kilogram of pseudoephedrine base is equivalent to greater than 20,000 pseudoephedrine HCl 60 mg dosage units. Therefore, the DEA proposes to reduce the threshold for pseudoephedrine. In order to ensure that OTC pseudoephedrine products remain available to those individuals who utilize these decongestants for legitimate medical purposes, the DEA proposes to establish the threshold for pseudoephedrine at a level consistent with personal use. As such, individuals who purchase below-threshold quantities intended for legitimate personal medical use, and retailers who sell below-threshold quantities for use by individuals for legitimate personal medical use, will not be adversely impacted by these regulations.

The Food and Drug Administration (FDA) has established a labeling requirement which sets the maximum adult daily dosage of pseudoephedrine at 60 mg every 6 hours or 240 mg per day. A 120 day supply of pseudoephedrine at the maximum daily recommended dose of 240 mg pseudoephedrine hydrochloride per day is equivalent to 28.8 gm of pseudoephedrine hydrochloride or 23.7 gm pseudoephedrine base. Therefore, the DEA proposes to establish a threshold of 24.0 grams pseudoephedrine base. Such a threshold will allow the purchase and sale of up to 120 day supply of pseudoephedrine for personal legitimate medical use, without the application of regulatory requirements. This will allow continued access to these products for legitimate use.

Waiver of Registration

In an effort to ensure the continued availability of pseudoephedrine products for legitimate personal use at the retail level, the DEA also proposes a waiver from registration for any retail distributor of regulated pseudoephedrine products. The authority for providing a waiver is clearly set forth in 21 U.S.C. Section 822(d) whereby ''The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.''

Therefore retail distributors (defined under 21 CFR 1309.02 as selling only personal use quantities to walk-in customers) of regulated pseudoephedrine products would not be required to obtain a DEA registration for such transactions.

As discussed later, it is estimated that there are approximately 750,000 retail distributors of pseudoephedrine in the U.S. Such a waiver would benefit the vast majority of these distributors. Firms engaging in above-threshold transactions of non-exempt pseudoephedrine products, however, would not be retail distributors. Therefore they would be required to obtain a DEA registration as a distributor, maintain records as specified in 21 CFR 1310.04 and report suspicious transactions as specified in

21 CFR 1310.05 notification requirement. In addition, all importers, exporters and other types of distributors of non-exempt pseudoephedrine products would be required to register with the DEA and would be subject to the full regulatory provisions of the Controlled Substances Act and the Controlled Substances Import and Export Act.

The clandestine manufacture and abuse of methamphetamine are serious national public health problems which require Federal action. Companies operating on the fringe of legitimate commerce are supplying these clandestine laboratories. In an effort to minimize the impact of the proposed regulations on the legitimate industry, the DEA has examined various options available.

The DEA is aware of the large scale legitimate use of OTC pseudoephedrine products and their widespread distribution at retail outlets. However, the DEA believes that the registration, recordkeeping, reporting and notification requirements that have been successfully used to limit the diversion of other chemicals to clandestine laboratories are needed to control this problem.

The DEA has determined that approximately 750,000 retail distributors and an undetermined number of other distributors would be impacted if pseudoephedrine products were made subject to the full extent of the CSA chemical regulatory provisions. However, in recognizing the need to limit the regulatory burden on handlers of pseudoephedrine products to the minimum level necessary to prevent the large scale diversion of these products for clandestine use, the DEA has taken significant steps to minimize the burden on the 750,000 retailers who sell these pseudoephedrine products.

First, given the large number of retail distributors who handle these products in the United States, the DEA has proposed that relief be provided by providing a waiver from registration for these distributors. Thus, the proposed regulations primarily impact distributors who are not classified as retail distributors. These distributors include mail-order and wholesale distributors. The DEA has attempted to identify the number of firms which will be impacted by these regulations. This review included consultation with industry associations and other Federal and local government agencies. These entities were only able to identify a limited number of newly affected firms.

Secondly, the DEA has limited controls to a specific group of products which have been demonstrated to be most readily used for illicit purposes. The DEA believes that this approach provides effective protection against diversion while minimizing the burden on industry. Thirdly, the proposed regulations allow for the purchase and sale of up to a 120 day supply of pseudoephedrine for personal legitimate medical use, without the application of regulatory requirements.

The DEA has consulted with the National Wholesale Druggists Association (NWDA) in an effort to determine the potential size of the impacted industry. According to NWDA sources, there are approximately 750,000 retail distributors in the U.S. which sell over-the-counter pseudoephedrine products.

In addition, the DEA has met with the Nonprescription Drug Manufacturers Association (NDMA) regarding the U.S. pseudoephedrine market and to obtain input on the distribution of pseudoephedrine for legitimate medical use. NDMA has further confirmed that there are approximately 750,000 retail distributors of over-the-counter products in the U.S. NDMA, which stated that its members account for the manufacture of over 90 percent of the over-the-counter drugs marketed domestically, informed DEA that member companies primarily distribute pseudoephedrine in package sizes ranging from 10 to 60 solid dosage units per package. In an effort to reduce the adverse impact upon those who sell and purchase pseudoephedrine products at the retail level, the DEA ensured that the proposed threshold was well above the standard package size manufactured by NDMA members and distributed by retail distributors. The proposed threshold of 24.0 grams pssudoephedrine base is equivalent to 488 pseudoephedrine hydrochloride 60 mg dosage units.

The primary impact of the proposed regulations will be upon those entities not classified as retail distributors. Such entities include mail-order distributors and wholesale distributors. The DEA has attempted to quantify the number of these distributors in the U.S. The NWDA informed the DEA that its 1993 Operating Survey indicated that 70 full-line drug wholesalers (who distribute both prescription and over-the-counter products) distributed nearly 80 percent of the prescription drugs in the U.S. in 1993. These full-line drug wholesalers operated approximately 230 distribution centers. Current information provided by NWDA indicates that due to consolidation within the drug wholesale industry, there are currently only approximately 50 full-line wholesale distributors supplying this market in the U.S.

These firms are already CSA registrants and as such would not need to obtain a separate registration under the proposed regulations (21 CFR 1309.25). In addition, the impact upon these full-line distributors will be minimized since, pursuant to 1310.06(b), normal business records shall be considered adequate if they contain the information required in 21 CFR 1310.06(a) and are readily retrievable from other business records.

The NWDA was unable to provide estimates of the percentage of the over-the-counter market supplied by these full-line distributors but informed DEA of the existence of other smaller wholesale distributors who only distribute over-the-counter pseudoephedrine products. These wholesale distributors will be impacted by the proposed regulations since they will be required to register with the DEA and ensure that records maintained are adequate to meet the requirements under Section 1310.06.

In addition to contact with the industry associations, the DEA has contacted the National Association of Boards of Pharmacy and individual State Boards of Pharmacy in an attempt to quantify the number of these distributors currently operating in the U.S. which will be impacted by these regulations. The DEA has not been successful in quantifying the number of these firms operating in the U.S. or in finding a professional association which represents these business entities. However, the State of Idaho licenses all business entities which distribute over-the-counter products into or within the state. The Idaho Board of Pharmacy indicated that the majority of the distributors are actually outside of Idaho and that only 418 distributors are licensed to distribute drug products into Idaho.

The DEA has attempted to limit the regulatory burden on pseudoephedrine handlers. The proposed regulations include provisions which ensure that the 750,000 retailers of pseudoephedrine will not be adversely impacted. These 750,000 retail distributors will not be required to register or maintain records unless they engage in transactions of a limited group of pseudoephedrine products in quantities which exceed a 120 day supply. Therefore the vast majority of retail distributors will not be impacted by these regulations.

While other types of distributors will be subject to the proposed regulatory controls, the DEA (in consultation with industry associations and other

government agencies) has been able to identify only a limited number of these newly affected firms. The DEA welcomes any information regarding the number of entities affected.

The Attorney General has delegated authority under the CSA and all subsequent amendments to the CSA to the Administrator of the DEA (28 CFR 0.100). The Administrator, in turn, has redelegated this authority to the Deputy Administrator pursuant to 28 CFR 0.104.

The Deputy Administrator has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

This proposed rule has been reviewed pursuant to the principles of Executive Order 12866. It has been determined that the proposed rule is not significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This proposed action has been analyzed in accordance with the principles and criteria in E.O. 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

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

21 CFR Part 1310

Drug traffic control, Reporting and recordkeeping requirements, List I and List II chemicals.

21 CFR Part 1313

Drug traffic control, Imports, Exports, Transshipment and in-transit shipments, List I and List II chemicals.

For reasons as set out above, 21 CFR Parts 1309, 1310 and 1313 are proposed to be amended as follows:

PART 1309—[AMENDED]

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.

2. Section 1309 is proposed to be amended by adding a new paragraph 1309.28 to read as follows:

§ 1309.28 Exemption of retail distributors of certain pseudoephedrine products.

The requirement of registration is waived for any retail distributor, for the distribution of any product containing pseudoephedrine that is regulated pursuant to Section 1310.01(f)(1)(iv)(A)(2). The term retail distributor, as defined in Section 1309.02(g), means a distributor whose List I chemical activities are restricted to the sale of drug products that are regulated as List I chemicals pursuant to Section 1310.01(f)(1)(iv), directly to walk-in customers for personal use. For purposes of this paragraph, sale for personal use means the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use. (The threshold of 24.0 grams pseudoephedrine base is equivalent to 488 pseudoephedrine hydrochloride 60 mg dosage units.)

3. Section 1309.71 is proposed to be amended by revising paragraph (a)(2) to read as follows:

§ 1309.71 General security requirements.

* * * * *

(a) * * *

(2) In retail settings open to the public where drugs containing List I chemicals that are regulated pursuant to Section 1310.01(f)(1)(iv)(A)(1) are distributed, such drugs will be stocked behind a counter where only employees have access.

* * * * *

PART 1310—[AMENDED]

1. The authority citation for Part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.01 is proposed to be amended by revising paragraph (f)(1)(iv)(A) to read as follows:

§ 1310.01 Definitions.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(A)(*1*) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term ''therapeutically insignificant quantities'' shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in current editions of the American Pharmaceutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in Section 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(*2*) The drug is an over-the-counter (OTC) solid dosage form product (tablet, capsule or powder packet) which contains pseudoephedrine or its salts, optical isomers, or salts of optical isomers but does not contain either acetaminophen, aspirin or ibuprofen in therapeutically significant quantities. For purposes of this paragraph, the quantities of either acetaminophen, aspirin or ibuprofen present in a pseudoephedrine drug product shall be considered to be present in ''therapeutically significant quantities'' if the product formulation (i.e. the qualitative and quantitative composition of active ingredients within the product) is listed in current editions of the American Pharmacoutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.); or the product is listed in Section 1310.15 as an exempt drug product. For drug products having a formulation not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients (acetaminophen, aspirin or ibuprofen) are present in quantities considered therapeutically significant for purposes of this paragraph; or

* * * * *

3. Section 1310.04 is proposed to be amended by revising paragraph (f)(1)(x) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(f) * * *

(1) List I Chemicals:

Chemical	Threshold by base weight
(x) Pseudoephedrine, its salts, optical isomers and salts of optical isomers.	24 grams.

* * * * *

4. Section 1310.14 is proposed to be amended by revising the heading and by revising paragraph (a) to read as follows:

§ 1310.14 Exemption of certain ephedrine or pseudoephedrine combination drug products.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in Section 1310.01(f)(1)(iv)(A)(1), or any manufacturer of a drug product containing pseudoephedrine in combination with acetaminophen, aspirin or ibuprofen, the product formulation of which is not listed in the compendiums set forth in Section 1310.01(f)(1)(iv)(A)(2), may request that the Administrator exempt the product as one which contains ephedrine together with therapeutically significant quantities of the other active medicinal ingredients or pseudoephedrine in combination with therapeutically significant quantities of acetaminophen, aspirin or ibuprofen.

* * * * *

5. Section 1310.15 is proposed to be amended by revising the heading, by revising paragraph (a), and by revising paragraph (d) to read as follows:

§ 1310.15 Exempt combination drug products containing ephedrine or pseudoephedrine.

(a) The drug products containing ephedrine in combination with therapeutically significant quantities of another active medicinal ingredient, or pseudoephedrine in combination with therapeutically significant quantities of acetaminophen, aspirin, or ibuprofen; listed in paragraph (e) of this section, have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

* * * * *

(d) In addition to the drug products listed in the compendium set forth in Section 1310.01(f)(1)(iv)(A)(1) and 1310.01(f)(1)(iv)(A)(2), the following drug products, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE IN COMBINATION WITH THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT AND EXEMPT DRUG PRODUCTS CONTAINING PSEUDOEPHEDRINE IN COMBINATION WITH THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ACETAMINOPHEN, ASPIRIN OR IBUPROFEN

Supplier	Product name	Form	Date
[Reserved]	.....	.....	.....

PART 1313—[AMENDED]

1. The authority citation for Part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is proposed to be amended by revising paragraph (d)(1)(iv)(A) to read as follows:

§ 1313.02 Definitions.

* * * * *

(d) * * *

(1) * * *

(iv) * * *

(A)(*1*) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term ''therapeutically insignificant quantities'' shall apply if the product formulation (i.e. the qualitative and quantitative composition of active ingredients within the product) is not listed in current editions of the American Pharmaceutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in Section 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(*2*) The drug is an over-the-counter (OTC) solid dosage form product (tablet, capsule or powder packet) which contains pseudoephedrine or its salts, optical isomers, or salts of optical isomers, but does not contain either acetaminophen, aspirin or ibuprofen in therapeutically significant quantities. For purposes of this paragraph, the quantities of either acetaminophen, aspirin or ibuprofen present in a pseudoephedrine drug product shall be considered to be present in ''therapeutically significant quantities'' if the product formulation (i.e. the qualitative and quantitative composition of the active ingredients within the product) is listed in current editions of the American Pharmaceutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.); or the product is listed in Section 1310.15 as an exempt drug product. For drug products having a formulation not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients (acetaminophen, aspirin or ibuprofen) are present in quantities considered therapeutically significant for purposes of this paragraph; or

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Dated: October 25, 1995.

Stephen H. Greene,

Deputy Administrator.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 14, 18, and 75

RIN 1219–AA92

Requirements for Approval of Flame-Resistant Conveyor Belts

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule; reopening of the record; request for public comment.

SUMMARY: The Mine Safety and Health Administration (MSHA) is reopening the rulemaking record to receive additional test data, technical information, and further comment on proposed revisions to its regulations for the approval of flame-resistant conveyor belts for use in underground coal mines. After the close of the public record, some commenters indicated to MSHA that they had obtained or would be obtaining flame test data and technical