8. Contact person: Enter the name of a person that can act as a contact for your firm if any questions arise concerning the information included in the notice.

9. Certification: The form is to be signed by a responsible individual for the firm that can certify to the authenticity of the information presented on the form. The individual signing the form will commit to notify the Office of Food Labeling when the numbers of full-time equivalent employees or total numbers of units of products sold in the United States exceed the applicable number for an exemption.

The completed form should be mailed to: Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St., SW, Washington, DC 20204. Questions concerning a claim may be directed to the Office of Food Labeling at the above address or to 202–205–4561.

[FR Doc. 96–20075 Filed 8–6–96; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310 and 1313

[DEA–138F]

RIN 1117–AA32

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This 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 regulatory chemical control provisions of the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act. This rule finalizes a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on October 31, 1995 (60 FR 55348).

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, guaifenesin or dextromethorphan. This action also reduces the threshold for pseudoephedrine to 48.0 grams pseudoephedrine base. Such a threshold is sufficient to permit the purchase of up to a 244 day supply of OTC pseudoephedrine drug products without the application of regulatory requirements. In addition, the cumulative threshold requirement for multiple transactions of pseudoephedrine drug products in a calendar month will not apply to sales for personal use. To further ensure the availability of pseudoephedrine products to legitimate consumers at the retail level, this action also waives the registration requirement for retail distributors of regulated pseudoephedrine products.

EFFECTIVE DATES: October 7, 1996. Persons seeking registration must apply on or before November 20, 1996, in order to continue to distribute, import or export pseudoephedrine products for which registration is required pending final action by the DEA on their application.

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

SUPPLEMENTARY INFORMATION: On October 31, 1995, the DEA published a Notice of Proposed Rulemaking (NPRM) which proposed the removal of the exemption for certain over-the-counter (OTC) pseudoephedrine products from the chemical control provisions of the Controlled Substances Act (CSA). The NPRM documented the increasing problem of OTC product diversion for use as precursor material in the clandestine production of methamphetamine.

The clandestine manufacture and distribution of methamphetamine are serious national public health problems which require Federal action. Methamphetamine, a Schedule II Controlled Substance, is the most prevalent controlled substance clandestinely synthesized in the United States. Between January 1, 1994 and December 31, 1995, the DEA has been involved in the domestic seizure of 587 methamphetamine laboratories. Ephedrine and/or pseudoephedrine were utilized as the precursor material at the vast majority of these laboratories.

The significance of the abuse of methamphetamine is well known and documented. In recent years the problem has increased dramatically. In 1994. alone, there were over 700 methamphetamine related deaths in the United States.

The DEA monitors Medical Examiner (ME) data from approximately 42 medical examiners located in major cities in the contiguous 48 states. Nationally, ME reported deaths related to methamphetamine increased 145% from 1992 to 1994 and there were 1816 deaths for the period 1991 to 1994. In addition, methamphetamine emergency room episodes increased significantly in 1993 and 1994. Current data indicate the illicit production, distribution and abuse of methamphetamine remain a serious problem.

In addition, 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.

The NPRM documented that pseudoephedrine was utilized in 22 percent of the laboratories seized from January 1, 1995 through September 1995. DEA thereby acted to place regulatory controls on these products in an effort to further minimize the availability of widely used precursor material and ultimately protect the public health. Since publication of the NPRM, the extent of diversion of OTC pseudoephedrine products has intensified in the United States. End of year data for 1995 indicates that at least 28 percent of the clandestine methamphetamine laboratories seized utilized pseudoephedrine.

In recent years, the diversion of OTC products has been the predominant source of precursor material for the clandestine synthesis of methamphetamine. As regulatory controls were implemented to counter the diversion of specific types of OTC products, clandestine laboratory operators have been successful in circumventing these controls to obtain precursor material through the diversion of millions of OTC dosage units of exempt products. The NPRM documents the progression of the diversion from bulk ephedrine, to single entity OTC ephedrine products, to OTC ephedrine combination products and OTC pseudoephedrine products.

As stated in the NPRM, since 1989 ephedrine has been the primary precursor used in the clandestine synthesis of methamphetamine in the United States. Clandestine laboratory operators exploited the lack of control 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 (Pub. L. 103–200) became effective on April 16, 1994. This Act further amended the CSA 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 United States 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 registration, 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 (21 U.S.C. 814) 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 distributors, importers and exporters.

The Chemical Diversion and Trafficking Act (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 disastereomers. 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 controlled substances.

The DEA is aware of the large scale legitimate use of OTC pseudoephedrine products and their widespread distribution. 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 for some pseudoephedrine products to control this problem.

The DEA has documented both mail order and retail diversion of OTC pseudoephedrine products for use in the clandestine production of methamphetamine. In proposing these regulations the DEA has specifically attempted to target both sources of the problem. In order for such regulatory action to be effective, it should include provisions which directly target the problem of indiscriminate distribution of wholesale level quantities by retail, mail order and wholesale distributors.

While there is an urgent need to counter the diversion of OTC pseudoephedrine products for the clandestine production of methamphetamine, these regulations go to extreme lengths to protect the availability of these pseudoephedrine decongestant products for legitimate medical use. While all mail order and wholesale distributors will be subject to the full extent of CSA chemical regulatory controls, specific exemptions and waivers have been provided for retail distributors selling personal use quantities so that these retail distributors are not adversely impacted.

In writing the NPRM, the DEA proposed the inclusion of four provisions which would eliminate potentially burdensome requirements for practically all of the estimated 750,000 retail distributors who would be impacted if pseudoephedrine products were made subject to the full extent of the CSA chemical provision established by law. First, the DEA has provided a waiver from registration for these distributors. Secondly, the DEA has limited controls to a specific group of products. Thirdly, the NPRM proposed the establishment of a threshold of 24.0 grams pseudoephedrine base and therefore would 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. In this final rule, this threshold has been increased to 48.0 grams. Such a threshold would allow for the purchase and sale of up to a 244 day supply of pseudoephedrine without the application of regulatory requirements. (A 244 day supply of pseudoephedrine at the maximum recommended FDA dosage of 240 mg/day would be 976 pseudoephedrine 60 mg tablets.) Lastly, the proposal specifies that the threshold quantity applies only to a single transaction. Therefore no cumulative threshold for multiple transactions applies to OTC pseudoephedrine transactions and there is no requirement to record each transaction as long as the individual transaction is below the threshold quantity.

Because of these provisions, no retail distributor will be required to register or maintain records as long as they distribute only below-threshold quantities in a single transaction. A retail distributor will only be required to reports suspicious regulated transactions to the DEA as per 21 CFR 1310.05.

Public Comments

Interested parties were provided with 60 days in which to comment on the proposed regulations. The DEA received a total of 17 comments. While the general tone of the comments was supportive of the need to counter the clandestine production of controlled substances such as methamphetamine, the commentors raised a number of concerns regarding specific provisions of the proposed regulation as follows:

(1) Five commentors requested that the comment period be extended. The

DEA responded that the 60 day comment period provided for in the NPRM was adequate and provided sufficient time for comments. Therefore the requests for extension were denied.

(2) In response to the NPRM, the National Association of Boards of Pharmacy (NABP) submitted a letter of strong support for the proposed regulations. NABP wrote that a nationwide Federal effort, under the auspices of DEA, was necessary to deal with the diversion of such OTC products and accordingly NABP supports the present effort to bring the diversion of drug products containing pseudoephedrine under control.

(3) Numerous commentors expressed concern that the term ''threshold quantity'' is not defined and that it is not clear in the NPRM whether the threshold is calculated on a single transaction or on a cumulative total of multiple purchases during a calendar month. These commentors stated that the proposed rule will affect the availability of pseudoephedrine products and retail distributors will be severely impacted by this proposal if a cumulative threshold applies. Commentors also expressed concerns that in order to ensure that a cumulative threshold was not exceeded during a calendar month, retailers would have to place non-exempt pseudoephedrine products behind the counter (thus creating a third class of drug products), maintain records of each and every transaction, register with the DEA and potentially pay large fines in the event that the cumulative threshold was exceeded. Several commentors stated that under such regulatory requirements they feared that retailers would cease to carry non-exempt pseudoephedrine products and these products would be placed at a competitive disadvantage. Commentors also stated that most of the distributors will not be able to afford or simply will not pay the registration fees and increased costs of paperwork associated with DEA registration or recordkeeping.

These commentors misread the proposal which states that the sale of non-exempt pseudoephedrine products in quantities below 24.0 grams pseudoephedrine base applies to a single transaction. The phrase ''in a single transaction'' was specifically included in § 1309.28 (Exemption for retail distributors) which states that the sale for personal use means the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use. The cumulative threshold requirements for multiple transactions of pseudoephedrine products within a calendar month will not apply to sales for personal use. Therefore, the DEA reemphasizes that retail sales of personal use quantities for legitimate medical use in a single transaction will *not* require (1) The placement of these pseudoephedrine products behind the counter, (2) maintenance of records for each transaction, or (3) registration with the DEA. In order to further clarify that the cumulative threshold requirements for multiple transactions of pseudoephedrine products within a calendar month will not apply to sales for personal use, §§ 1309.28 and 1310.04 have been modified accordingly. In addition, § 1309.71 has been modified to reflect that the requirement that certain drug products to be stocked behind a counter where only employees have access does not apply to drugs containing List I chemicals that are regulated pursuant to § 1310.01(f)(1)(iv)(A)(*2*).

(4) Several commentors stated that the NPRM does not present sufficient evidence of the scope, duration and significance of OTC pseudoephedrine diversion to justify the proposed action.

The NPRM addresses each of these issues and includes a thorough discussion of the evolution and extent of the diversion of OTC drug products as precursor material for the clandestine synthesis of methamphetamine in the United States. The NPRM also describes actions taken to counter such diversion and specifically outlines steps taken by clandestine laboratory chemist to circumvent controls implemented at the Federal level.

On October 31, 1995, the DEA published the NPRM in an attempt to counter the growing problem of pseudoephedrine diversion and thereby protect the public health and safety. This NPRM notes that (as of the date of publication) 22 percent of the methamphetamine laboratories seized in 1995 in the United States utilized pseudoephedrine as the precursor material. In addition, the NPRM documents specific increases in the percentage of clandestine methamphetamine laboratories using pseudoephedrine as precursor material between 1994 and 1995.

Since publication of the NPRM, all indicators show clear evidence that the scope of the diversion of pseudoephedrine for the clandestine synthesis of methamphetamine continues to grow.

Current data indicates that the DEA was involved in the seizure of 327 methamphetamine laboratories in calendar year 1995 and that at least 28 percent of these laboratories utilized pseudoephedrine as the precursor material. Smuggling of bulk powder has not been shown to be a significant source of pseudoephedrine for use at these laboratories and investigative data indicates that essentially all pseudoephedrine utilized involved the diversion of OTC pseudoephedrine products.

In regard to the significance of the problem, the adverse impact of methamphetamine abuse in the United States is clear. The NPRM clearly documents that the production of methamphetamine is the United States' most significant clandestine laboratory problem.

Nationally, over 700 methamphetamine related deaths were documented in the United States in 1994. In addition, there is substantial evidence that the abuse of methamphetamine is associated with violent behavior and criminal activity. Coupled with the public health and safety consequences from the abuse of methamphetamine, the extensive use of pseudoephedrine as precursor material (in 28 percent of 1995 seized laboratories) provides overwhelming support for the need to control OTC pseudoephedrine products in a manner which prevents their use as precursor material while permitting the unencumbered sale for legitimate use. In proposing these pseudoephedrine regulations, the DEA acted in a timely manner to counter a growing public health and safety problem. The increase in seizures of methamphetamine laboratories utilizing pseudoephedrine further justifies the proposed regulations.

(5) Two commentors stated that the exemption for retail distributors arbitrarily discriminates against other legitimate distributors who provide consumers with convenience and savings of shopping at home (such as mail order distributors). One of these commentors further stated that the registration exemption is being provided to businesses (such as retail distributors) which have the least ability to monitor sales. In contrast, however, several commentors stated the converse. Specifically these commentors stated that the DEA should restrict its efforts to target mail order distribution and not impact retail distribution activity.

The issue pertaining to the exclusion of mail order activities from the definition of retail distributor was addressed in the June 22, 1995, Federal Register Notice (60 FR 32447) which implemented provisions of the DCDCA. As stated in that notice, it has been DEA's experience that mail order distributors deal with both individuals and businesses, the volume of product

sales can be quite large, and such firms are often less readily able to positively identify their customers. In addition, investigations will be significantly more complex and time consuming for a mail order distributor than a retail distributor. It is therefore appropriate that mail order activities not be provided the same waiver as retail distributors.

In addition several commentors stated that the DEA has no evidence of retail diversion and instead should target the source of the problem such as mail order distributors. In response to these comments, the DEA has documented both mail order and retail diversion of OTC pseudoephedrine products for use in the clandestine production of methamphetamine. In implementing these regulations the DEA is specifically attempting to target both sources of the problem. In order for such regulatory action to be effective, it should include provisions which directly target the problem of indiscriminate distribution of wholesale level quantities by retail, mail order and wholesale distributors.

While all mail order and wholesale distributors will be subject to the full extent of CSA chemical regulatory controls, specific exemptions and waivers have been provided for retail distributors selling personal use quantities. However, the regulation will affect large sales of non-exempt pseudoephedrine products by retail distributors. The following are several anecdotal examples of the diversion of pseudoephedrine which illustrate the need for regulating large purchases of pseudoephedrine that are not consistent with personal use quantities at all levels of distribution.

The following are several examples of retail diversion: DEA has documented that individuals have successfully solicited pharmacists to order and sell excessive quantities of 60 mg pseudoephedrine OTC tablets. The DEA was initially notified by a pharmacist employee of a large chain pharmacy of an excessive pseudoephedrine purchase. DEA met with the pharmacist and was informed that the purchaser initially requested 300 pseudoephedrine 60 mg tablets but gradually increased his request to 10,000 pseudoephedrine 60 mg tablets. The pharmacist subsequently ordered and received the 10,000 tablets which the individual picked up and paid for in cash. The individual then requested a second order be placed for 50,000 pseudoephedrine 60 mg tablets which the pharmacist ordered and received. When the individual telephoned to inquire whether the order had been received, the pharmacist further questioned the individual about the intended purpose. After this phone conversation, however, the individual neither picked up his order or called the pharmacy again. DEA then conducted a random survey of other pharmacists in the nearby area for pseudoephedrine purchases. DEA investigators found that the same individual had also ordered excessive quantities from three other retail pharmacies. The individual ordered 20,000 pseudoephedrine 60 mg tablets, 100,000 tablets and 100,000 tablets respectively from these other pharmacies. At each of the retail distributors, the same individual had given different reasons for needing the pseudoephedrine.

In an unrelated incident, the DEA was notified of a large purchase of pseudoephedrine tablets by a large chain pharmacy in California. Further investigation revealed that an individual had taken a bottle of pseudoephedrine off the shelf and requested that the pharmacy staff place a large order for the product on his behalf. Upon consultation with the pharmacist-in-charge, an order for 4,000 bottles was placed. According to pharmacy records, the pharmacy had purchased a total of 550,000 pseudoephedrine tablets in five separate orders over a 3 month period. The individual never provided any identification, address or telephone number and always called the pharmacy to ask if the order had come in. After placing several orders, the pharmacist learned from a third party that pseudoephedrine tablets may be used to manufacture methamphetamine. At that point the pharmacist informed the individual that she would not order any more tablets because of possible misuse.

In a separate action, the DEA was notified by a large retail drug chain that individuals had just purchased about $800 worth of pseudoephedrine tablets from four of their pharmacies. A license plate check revealed that the vehicle utilized at the time of purchase belonged to the wife of a DEA fugitive and subject of a state methamphetamine investigation. During the investigation, investigators also learned of an unrelated purchase from another retail pharmacy whereby an individual attempted to order and purchase 100,000 pseudoephedrine tablets for ''export purposes'' to the Orient.

In an another incident, the DEA received a call from loss prevention personnel for a large chain drug store advising of two incidents of pseudoephedrine diversion that day. The entire inventory of pseudoephedrine product was purchased off the shelf of the pharmacy through 3 purchases. The purchases were made in cash.

In a separate case, DEA served an administrative subpoena on a pharmacy for records of receipt and sales of pseudoephedrine tablets. When the subpoena was served, DEA investigators found the pharmacy manager hiding in an adjacent room. After a consent to search, the DEA seized 300,000 pseudoephedrine tablets and $65,000 cash at the pharmacy. Agents later seized an additional $50,000 cash from a vehicle belonging to an individual who came to the pharmacy to buy pseudoephedrine from the pharmacy manager.

In mid 1995, two retail distributors were identified as selling large quantities of OTC pseudoephedrine. During an 8 month period one retailer sold 70,000 pounds of pseudoephedrine tablets and the second retail distributor sold approximately 8,500 pounds of pseudoephedrine tablets. As a result of an investigation into these excessive sales, several employees and individuals associated with these establishments were arrested by DEA.

In another instance, with the arrest of an individual for possession and manufacture of methamphetamine, DEA investigators found 3 liters of methamphetamine and sufficient chemicals for the production of approximately one kilogram of methamphetamine. In addition, investigators found pseudoephedrine/antihistamine combination OTC tablets (consisting of pseudoephedrine 60 mg and triprolidine 2.5 mg) and receipts for the purchase of OTC pseudoephedrine tablets from a local chain drug store. Later, investigators interviewed the drug store manager and reviewed store cash register receipts which documented the sale of pseudoephedrine combination OTC tablets.

The following are several examples which illustrate the magnitude of mail order diversion:

In October of 1995, the DEA seized a large methamphetamine laboratory utilizing pseudoephedrine capable of manufacturing 200 pounds of methamphetamine per month. Precursor material was obtained through the mail order purchase of OTC pseudoephedrine tablets.

In a long term DEA methamphetamine investigation, DEA seized 7.5 million dosage units of OTC pseudoephedrine and 1.8 million OTC ephedrine dosage units and other chemicals used in the manufacture of methamphetamine. The OTC products used as precursor material were obtained through mail order distributors. In the course of the investigation over 7.8 million dollars

was seized from the trafficking organization.

In another investigation, after the undercover purchase of 20 million pseudoephedrine tablets from an OTC manufacturer and distributor, DEA seized 25 metric tons of pseudoephedrine, ephedrine and phenylpropanolamine. Five tractor trailer trucks were required to remove the material to a secure storage facility. The company, which dealt extensively in mail order distribution, has been identified as purchasing 191 metric tons of pseudoephedrine and ephedrine between January 1994 and May 1995.

The above examples of significant diversion illustrate the need for regulation at all levels of distribution of non-personal use quantities, whether it be wholesale, retail or mail order distribution.

(6) One commentor noted that agencies are required to prepare and make available for public comment an initial regulatory flexibility analysis which describes the impact of a proposed rule on small entities. This commentor states that the NPRM is therefore deficient in that it does not adequately set forth such an analysis. The commentor did, however, recognize that this provision does not apply to instances where the head of the agency certifies that the rule will not have significant impact on a substantial number of small entities.

The NPRM documents the various provisions which were specifically provided in order to minimize the impact on small businesses. These provisions were the result of a reasoned analysis of the potential impact of implementation of the full extent of CSA regulations on the affected industry and small businesses in particular. In providing for these special provisions, DEA gave special care and consideration to industry concerns and given these provisions, ensured that these regulations ''will not have significant impact on a substantial number of small entities''.

As previously stated in the NPRM, the DEA met with and consulted with industry representatives prior to proposing these regulations in an effort to minimize any adverse impact. In addition, the NPRM specifically details provisions designed to eliminate the adverse impact on small businesses at the retail level. First, the DEA proposed that retail distributors not be subject to registration. Secondly, the DEA has limited controls to a specific group of products. Thirdly, the NPRM proposed the establishment of a threshold of 24.0 grams pseudoephedrine base and therefore would 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 proposed threshold was subsequently raised to 48.0 grams in this final rule. Lastly, the NPRM specifies that the threshold quantity applies only to a single transaction.

(7) One commentor suggested that small package sizes would be enormously expensive to divert and implied that these products therefore would not be cost effective sources of pseudoephedrine as precursor material for the synthesis of methamphetamine. Prior to proposing these regulations, however, the DEA reviewed the cost of various brand name pseudoephedrine products in various package sizes and formulations. The DEA undertook this examination for the specific purpose of determining whether certain products should remain exempt from the proposed regulations based solely on the fact that their use in the synthesis of methamphetamine would not be financially profitable. This review indicated that even the most expensive brand name pseudoephedrine dosage form products (including the more expensive syrups and products containing multiple active ingredients) would be cost effective sources of precursor material.

(8) Several commentors stated that the DEA has not provided a rationale for its selection of the group of drugs whose legal exemption would be revoked. These commentors stated that the NPRM provides insufficient scientific explanation as to why the exemption was removed for certain products. One commentor challenged that its scientists state that removal of pseudoephedrine in combination with antihistamines, guaifenesin and dextromethorphan is at least as difficult, if not more so, than analgesics and less efficient than from liquids, syrup and soft gelatin capsules. The commentor further stated that the DEA must consider whether the drug or group of drugs are formulated in such a way that cannot be easily used in the illicit production of controlled substances.

As stated in the NPRM, the DEA performed a review of the various pseudoephedrine dosage forms and available combinations of ingredients to determine which products are (1) formulated in such a way that the product itself cannot be easily used in the illicit production of methamphetamine; and (2) whether pseudoephedrine can be readily recovered from the product. In making determinations as to which product formulations should be subject to control, the DEA laboratory system undertook a study which utilized different types of OTC pseudoephedrine dosage forms and combinations of ingredients to see which of these formulations were most easily used in the clandestine synthesis of controlled substances using the procedures most commonly utilized by clandestine chemists. In addition, the study assessed whether pseudoephedrine could be readily extracted using clandestine laboratory techniques. In making its conclusions regarding which products and formulations should be regulated, the DEA considered, among other information, which products and formulations required modifications to normal clandestine manufacturing or extraction procedures and therefore required a more extension knowledge of chemistry. In response to comments that the DEA should elaborate further on its studies to determine the simplicity with which products may be converted to methamphetamine, the disclosure of such information would only serve to educate clandestine laboratory operators as to how to better produce methamphetamine and reveal which pseudoephedrine formulations provide the easiest source of precursor material.

(9) One commentor questioned the basis for DEA's claim that certain formulations and products can not be readily recovered. The commentor stated that liquids would be easier to convert and that the DEA provided no explanation as to why aspirin, acetaminophen or ibuprofen combinations are less likely to be diverted for clandestine use. In response to this comment, in attempting to manufacture methamphetamine from liquid formulations and combination products having formulations which contained an analgesic, DEA found that when a typical clandestine laboratory procedure was utilized, it was necessary to modify the manufacturing procedure in order to achieve acceptable results.

In determining which products should be subject to CSA chemical regulatory controls, the DEA has taken a conservative approach. As such, exemptions are being removed only for those products which *did not* require procedural changes when a typical methamphetamine clandestine manufacturing procedure was utilized. The exemptions are being retained for all pseudoephedrine products which required changes in these procedures.

(10) Several commentors stated that the NPRM would require training of employees to recognize a threshold transaction. The DEA acknowledges that retail distributors will need to provide instruction to their personnel so that

they are able to recognize an above-threshold transaction. In consultation with industry, the DEA has been informed that the most common package sizes range from 10 to 60 solid dosage units per package at the retail level. In proposing the establishment of the threshold of 24.0 grams pseudoephedrine base the DEA specifically ensured that such common package sizes are not adversely impacted.

DEA believes that the identification of above-threshold transactions will not be difficult, given package sizes routinely sold at the retail level. For example, one commentor stated that the vast majority of their brand name pseudoephedrine product is sold in package sizes of 24 dosage units or less with each unit containing 30 mg or 60 mg pseudoephedrine hydrochloride. Such packages would only contain between 0.6 grams and 1.2 grams pseudoephedrine base. An above-threshold purchase of greater than 24.0 grams of pseudoephedrine base contained in such products would be conspicuous and thereby difficult to conceal. An individual would have to purchase more than 976 dosage units of a 30 mg/dosage unit product. In the package size indicated, this would involve the purchase of more than 40 packages of such a product in a single transaction. For a 60 mg per dosage unit product packaged in bottles of 24 tablets, an above-threshold purchase would involve the purchase of over 488 dosage units in greater than 20 packages. Given the large size of the above transactions, it is not unreasonable to expect that retail distributors should be able to instruct personnel to recognize such conspicuous quantities in a single transaction.

Several commentors stated that in determining whether a transaction is above-threshold, retail distributors would have to differentiate between exempt and non-exempt pseudoephedrine products. These commentors stated that in the event that exempt and non-exempt pseudoephedrine products are both purchased in a single transaction, it will be difficult to determine whether the threshold has been exceeded.

In response to this comment, if both exempt and non-exempt pseudoephedrine products are purchased in a single transaction, the quantities of OTC cough-cold medication necessary to exceed the pseudoephedrine threshold would be even larger and more conspicuous than the quantities outlined above. The comment submitted by the National Association of Chain Drug Stores (NACDS) mentioned point of sale scanning as a possible way to monitor threshold quantities in a single transaction.

While the DEA believes that such transactions at the proposed threshold of 24.0 grams would be conspicuous and therefore easy to identify, the DEA has decided that in an effort to further reduce any potential burden on retailers, the threshold for pseudoephedrine will be increased to 48.0 grams. This quantity is double the proposed threshold. This would allow for the below-threshold purchase of 976 dosage units of a pseudoephedrine 60 mg product or 1953 dosage units of a 30 mg product in a single transaction. Such transactions would be sufficient for at least a 244 day supply of pseudoephedrine in a single transaction at the maximum recommended FDA dosage.

Concerns regarding the difficulty in providing instruction to employees to recognize a threshold transaction are therefore minimized by the implementation of the larger threshold and the magnitude of an above-threshold transaction. To further assist retailers in providing instruction to employees, the DEA will make available for distribution through industry associations, notices which provide further clarification of which pseudoephedrine products are regulated and guidance in recognizing a threshold transaction.

Given the large quantities of product necessary to exceed a threshold of 48.0 grams, it is not unreasonable to expect that retail distributors should be able to provide the rudimentary instruction necessary to recognize such conspicuous quantities. Retail distributors dealing only in quantities below these levels will not have to register with DEA and will not have to maintain records of transactions. Therefore, any impact on retail distributors is minimal

While the DEA has established the threshold at 48.0 grams (pseudoephedrine base) to permit the unregulated purchase of up to a 244 day supply at the maximum FDA recommended dosage of 240 mg pseudoephedrine HCl per day, the DEA is in no way encouraging consumers to exceed or ignore the warnings contained on the labeling of these pseudoephedrine products. This labeling, which is required by the FDA, warns that ''if symptoms do not improve within 7 days or are accompanied by a fever, consult a doctor''. In addition, some pseudoephedrine products warn the consumer ''Do not take this product for more than 7 days.'' Therefore, when the product is used in a manner consistent with its labeling, the purchase of a threshold quantity of 48.0 grams, will far exceed a 244 day supply of pseudoephedrine for personal legitimate medical use.

(11) Several commentors stated that before taking action against OTC pseudoephedrine products, the DEA should first use the enforcement tools such as registration requirements that Congress imposed under the DCDCA. In response to this comment, the DCDCA amended 21 U.S.C. 822 and 21 U.S.C. 823 to require registration of handlers of List I chemicals. However, the DCDCA stated that registration ''shall not be required for the distribution of a drug product that is exempted under section 102(39)(A)(iv).'' Therefore, registration requirements implemented under the DCDCA would not pertain to handlers of OTC pseudoephedrine products lawfully marketed under the Federal Food, Drug and Cosmetic Act. Since the DEA has already seen a shift toward the utilization of OTC pseudoephedrine products in clandestine laboratories, the registration of only bulk handlers of pseudoephedrine and ephedrine products would have no direct beneficial impact on preventing the diversion of these products.

(12) One commentor raised concerns that under the CSA chemical regulatory provisions, records will have to be maintained for a period of 4 years rather than a 2 year period. The commentor further states that while normal business records are adequate to meet the CSA regulatory requirements, the retention requirement will increase the recordkeeping burden. In response to this comment, the 4 year recordkeeping requirement for the chemical control provisions of the CSA was legislated by Congress (21 U.S.C. 830) and therefore is not within DEA's authority to change.

(13) One commentor requested a 45 day grace period allowing sales of covered products pending DEA action on registration applications. The commentor noted that, as written, the NPRM appears to prohibit above-threshold pseudoephedrine sales between the date the rule is finalized and the date registration is approved by DEA.

DEA agrees. In response to this comment, DEA has determined that each person required to obtain a registration because of implementation of this rule will be temporarily exempted from the registration requirement until the person has made proper application and the Administration has approved or denied such application, provided that the

application has been submitted within 45 days following the effective date of this regulation. (Section 1310.09 has been modified to reflect this.) This exemption only applies to the registration requirement; all other chemical control requirements set forth under the CSA will be in full force and effect as of the effective date of this regulation.

(14) One commentor noted that its independent distributors do not squarely meet the definition of ''retail distributors'' as defined as sales directly to ''walk-in'' customers for personal use. This commentor stated that most of their transactions are face-to-face but not walk-in. The commentor requested that the definition of retail distributor as set forth in Section 1309.02(g) be modified.

DEA agrees. Therefore, the DEA is modifying §§ 1309.28 and 1309.02(f) to reflect that the term retail distributor 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 § 1310.01(f)(1)(iv), in face-to-face transactions directly to individuals for personal use. The intent of this provision is for the distributor to be in the physical presence of the individual who is acquiring the pseudoephedrine for personal use.

In addition, the commentor noted that some distributions are from one of their independent distributors to another of their independent distributors. The commentor requested that these sales also be exempt since they are primarily below-threshold. However, the DEA has determined that these types of transactions do not meet the definition of retail distributor since such transactions would be intended for further distribution and would not be intended for personal use.

(15) One commentor requested clarification of the registration requirement for pharmacies. This commentor stated that because pharmacies are already registered, it could be implied that they would be subject to recordkeeping and reporting requirements.

In response to this request, pharmacies that do not engage in above-threshold transactions are treated the same as other retail distributors. However, pharmacies that sell above-threshold quantities in a single transaction will not meet the definition of retail distributor and will be required to register with DEA. In order to avoid the imposition of duplicative registration requirements on these registrants, 21 CFR 1309.25 provides for an exemption from chemical registration for controlled substance registrants. Although these entities will not be required to obtain a separate chemical registration, they will be required to comply with other chemical regulatory requirements such as recordkeeping and reporting requirements. Therefore, these pharmacies which sell above-threshold quantities of regulated pseudoephedrine products will be required to maintain a record of each transaction which exceeds the threshold in a single transaction and report any suspicious regulated transactions to the DEA.

(16) Two commentors inquired whether the exemption for their specific pseudoephedrine products could be reinstated if the products were modified in such a way that prevented their use as precursor material. In response to this comment, the DCDCA includes specific provisions for reinstatement of exemptions for particular drug products (21 U.S.C. 814). The DCDCA provides that upon application by a manufacturer of a particular drug product that has been removed from exemption, the exemption shall be reinstated with respect to the particular drug product if it is determined to be manufactured and distributed in a manner that prevents diversion. The DCDCA further states that factors to be considered shall include (1) the package sizes and manner of packaging of the drug product; (2) the manner of distribution and advertising of the drug product; (3) evidence of diversion of the drug product; (4) any actions taken by the manufacturer to prevent diversion of the drug product; and (5) such other factors as are relevant to and consistent with the public health and safety.

One commentor raised concerns regarding the limitation that only manufacturers may petition for reinstatement of the regulatory exemption of a specific product. This commentor stated that the regulations should be amended to allow distributors of private-brand products or any interested party to submit applications for reinstatement of exemption. In response to this request, please note that this provision was legislated by Congress under the DCDCA (21 U.S.C. 814) and specifies that ''on application by a manufacturer of a particular drug product'' the exemption may be reinstated if the particular drug product is manufactured or distributed in a manner that prevents diversion. Any such change would require Congressional legislation.

(17) Two commentors requested a hearing on the proposal pursuant to 21 U.S.C. 875. In response to these requests, unlike other rulemaking conducted pursuant to the CSA, the present rulemaking presents no requirement that the rule be made on the record after opportunity for a hearing. For example, 21 U.S.C. 811(a) requires the opportunity for a hearing whenever there is a proposed rescheduling of controlled substances. In addition, 21 U.S.C. 875 identifies general powers available to the DEA when exercising its authority under the CSA. Thus, 21 U.S.C. 875 complements existing hearing provisions under the CSA rather than conferring independent hearing authority. In any event, the DEA believes that the notice and comment conducted pursuant to this rulemaking enabled interested parties to provide meaningful comment on the final rule.

(18) One commentor stated that the rule is a significant regulatory action and should be reviewed by the Office of Management and Budget. This commentor also noted that the rule could have an annual effect on the economy of $100 million or more.

As outlined above, these regulations go to great lengths to avoid impacting retail distribution of these OTC products. Since the vast majority of distributors who handle these products will not need to register or maintain records, the economic impact of this proposal is extremely small. This rule is therefore not a significant regulatory action.

Final Rule

After careful consideration of each of the above comments, this regulation is finalized as follows:

Removal of Exemption

21 U.S.C. 814(a) provides that the Attorney General shall remove from exemption under 21 U.S.C. 802(39)(A)(iv) and 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.

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, 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 Federal 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 removing the exemption under 21 CFR 1310.01(f)(1)(iv) and 21 CFR 1313.02(d)(1)(iv) for OTC solid dosage form pseudoephedrine products (i.e. tablets, capsules and powder packets) lawfully marketed under the Federal 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 ingredients 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) and 21 CFR 1313.02(d)(1)(iv) will remain for liquids, syrups, and soft gelatin capsules containing pseudoephedrine (regardless of formulation) 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 Federal Food, Drug, and Cosmetic Act. In addition, the final regulations allow pseudoephedrine prescription products, regardless of the product formulation, to remain exempt from the final regulations, given existing distribution and dispensing requirements already imposed under the Federal Food, Drug and Cosmetic Act.

While certain pseudoephedrine products remain exempt from the regulatory controls of the CSA, all pharmaceutical products containing pseudoephedrine are List I chemicals, and as such, are subject to the criminal provisions of the CSA. Specifically, 21 U.S.C. 841(d) provides that any person who possesses or distributes any listed chemical knowing, or having reasonable cause to believe that it will be used to manufacture a controlled substance, shall be fined in accordance with Title 18, or imprisoned not more than 10 years, or both.

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 groups of pseudoephedrine products is limited to that currently necessary to prevent the diversion of pseudoephedrine products to illicit methamphetamine laboratories.

Revision of Threshold

The threshold for pseudoephedrine is being changed from 1.0 kilogram to 48.0 grams pseudoephedrine base 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 in equivalent to greater than 20,000 pseudoephedrine HCl 60 mg dosage units. Therefore the DEA is reducing 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 is establishing the threshold for pseudoephedrine at a level which will have no impact on 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 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 244 day supply of pseudoephedrine at the maximum daily recommended dose of 240 mg pseudoephedrine hydrochloride per day is equivalent to 58.56 grams of pseudoephedrine hydrochloride or 47.97 grams pseudoephedrine base. Therefore the DEA is establishing a threshold of 48.0 grams pseudoephedrine base. Such a threshold will allow the purchase and sale of up to a 244 day supply of pseudoephedrine for personal legitimate medical use at the maximum FDA recommended dosage, 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 is providing a waiver from registration for any retail distributor of regulated pseudoephedrine products. Therefore retail distributors (defined under 21 CFR 1309.02) of regulated pseudoephedrine products will not be required to obtain a DEA registration to distribute personal use quantities of OTC pseudoephedrine to individuals for legitimate medical use. 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.''

As discussed, it is estimated that there are approximately 750,000 retail distributors of pseudoephedrine in the United States. Such a waiver will benefit the vast majority of these distributors. Firms engaging in above-threshold transactions of non-exempt pseudoephedrine products, however, will not be considered retail distributors. Therefore they will be required to obtain a DEA registration as a distributor, maintain records as specified in 21 CFR 1310.04 and report suspicious regulated transactions as specified in 21 CFR 1310.05 notification requirement. In addition, all importers, exporters and other types of distributors (such as mail order distributors) of non-exempt pseudoephedrine products will be required to register with the DEA and will be subject to the full regulatory provisions of the CSA Act and the Controlled Substances Import and Export Act.

Conclusion

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 with needed precursor material such as ephedrine and pseudoephedrine. In an effort to minimize the impact of the final 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 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 while this regulation will necessitate that retail distributors of regulated pseudoephedrine products instruct employees to recognize a threshold transaction, the level of instruction needed is minimal, given the magnitude of the quantities needed to exceed the threshold in a single transaction. In addition, the vast majority of retail distributors deal only in quantities far below the threshold in a single transaction and therefore will not need to register with the DEA and will not need to maintain records. Therefore the Deputy Administrator certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

The Drug Enforcement Administration has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866 Section 3(f) and the Office of Management and Budget (OMB) has waived its review under section 6(a)(3)(A) of the order.

This final action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the final 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, List I and List II chemicals, Security measures.

21 CFR Part 1310

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

21 CFR Part 1313

Drug Traffic Control, Exports, Imports, List I and II chemicals, Transshipment and in-transit shipments.

For reasons as set out above, 21 CFR Parts 1309, 1310 and 1313 are 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 1309.02 is amended by revising paragraph (g) to read as follows:

* * * * *

(f) The term *retail distributor* 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) of this chapter, in face-to-face transactions directly to individuals for personal use. For purposes of § 1309.28, sale for personal use means the sale of below threshold quantities in a single transaction to an individual for legitimate medical use.

3. Section 1309.28 is added 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 § 1310.01(f)(1)(iv)(A)(*2*) of this chapter. The term *retail distributor*, as defined in § 1309.02(f), 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 § 1310.01(f)(1)(iv) of this chapter, in face-to-face transactions directly to individuals 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 cumulative threshold requirements for multiple transactions within a calendar month will not apply to sales for personal use of any product containing pseudoephedrine that is regulated pursuant to § 1310.01(f)(1)(iv)(A)(*2*) of this chapter. (The threshold of 48.0 grams pseudoephedrine base is equivalent to 976 pseudoephedrine hydrochloride 60 mg dosage units.)

4. Section 1309.71 is 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 § 1310.01(f)(1)(iv)(A)(*1*) of this chapter are distributed, such drugs will be stocked behind a counter where only employees have access. This requirement does not apply to drugs containing List I chemicals that are regulated pursuant to § 1310.01(f)(1)(iv)(A)(*2*) of this chapter.

* * * * *

21 CFR part 1310 is amended as follows:

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 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. (This provision applies only to OTC pseudoephedrine products and does not include those pseudoephedrine products dispensed only pursuant to a prescription.) 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 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 § 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 § 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 amended by revising the introductory text in paragraph (f) and paragraph (f)(1)(x) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(f) Except as provided in § 1309.28 of this chapter for sales for personal use, for those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a calendar month to be utilized in determining whether a receipt, sale, importation, or exportation is a regulated transaction is as follows:

(1) List I Chemicals:

Chemical	Threshold by base weight
(x) Pseudoephedrine, its salts, optical isomers and salts of optical isomers.	48 grams.

* * * * *

4. Section 1310.09 is revised to read as follows:

§ 1310.09 Temporary exemption from registration.

Each person required by section 3(b) of the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200, effective April 16, 1994), to obtain a registration to manufacture, distribute, import, or export a list I chemical (other than those list I chemicals exempted under § 1310.01(f)(1)(iv)), is temporarily exempted from the registration requirement. The registration exemption will remain in effect for each person until the person has made proper application for registration and the Administration has approved or denied such application, provided that the application has been submitted within 45 days following the effective date of the regulations in part 1309 implementing the Domestic Chemical Diversion Control Act of 1993. In addition, each person required to obtain a registration to manufacture, distribute, import, or export a drug or group of drugs removed from exemption under § 1310.01(f)(1)(iv) is also temporarily exempted from the registration requirement. The registration exemption will remain in effect for each person until the person has made proper application for registration and the Administration has approved or denied such application, provided that the application has been submitted within 45 days following the effective date of the regulation which eliminates the exemption under § 1310.01(f)(1)(iv). These registration exemptions apply only to registration; all other chemical control requirements set forth in the Domestic Chemical Diversion Control Act of 1993 and in parts 1310 and 1313 of this chapter remain in full force and effect.

5. Section 1310.14 is 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 § 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 § 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.

* * * * *

6. Section 1310.15 is 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 (d) 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 §§ 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].	.....	.....	

21 CFR part 1313 is amended as follows:

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 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 quanitative 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 § 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. (This provision applies only to OTC pseudoephedrine products and does not include those pseudoephedrine products dispensed only pursuant to a prescription.) 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 § 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 § 1310.14, whether the active medicinal ingredients (acetaminophen, aspirin or ibuprofen) are present in quantities considered therapeutically significant for purposes or this paragraph; or

* * * * *

Dated: May 9, 1996.

Stephen H. Greene,

Deputy Administrator.

Note: The following text will not appear in the Code of Federal Regulations.

Appendix

On May 9, 1996 the Deputy Administrator of the Drug Enforcement Administration (DEA) signed the above rule which finalizes a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on October 31, 1995 (60 FR 55348). At the request of the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs, the rule was provided to OMB for review on May 16, 1996. OMB cleared the final rule for publication on July 22, 1996. In the interim, however, 5 U.S.C. 605(b) was amended to require that at the time of publication of a final rule, the agency shall publish a statement providing the factual basis for the certification that the rule will not have a significant economic impact on a substantial number of small entities. While the issue of whether this rule will have a significant economic impact on a substantial number of small entities was addressed in this final rule, DEA is providing the information in this appendix to insure compliance with the amendments to 5 U.S.C. 605(b), which became effective on June 27, 1996, after the final rule was signed.

In making a determination that the rule will not have a significant economic impact on a substantial number of small entities, the DEA conducted a review of the affected industry. In performing this review, the DEA carefully considered regulatory alternatives and the potential impact of each regulatory alternative on the affected industry and small businesses in particular.

The clandestine manufacture and abuse of methamphetamine are serious national public health problems which require Federal action. Pseudoephedrine products produced to meet legitimate medical needs are diverted by clandestine laboratory operators for use as precursor material for the production of methamphetamine.

The DEA is aware of the large scale legitimate use of the over-the-counter (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. In writing this regulation, the DEA considered various levels of regulatory control on pseudoephedrine products. These options ranged from the establishment of no controls on pseudoephedrine products to the imposition of the full extent of controls permitted under existing statutory authority. Given the magnitude of documented deaths due to methamphetamine and the untold cost of violence and crime associated with methamphetamine abuse, the DEA determined that some measure of control is necessary and therefore the establishment of no regulatory control on pseudoephedrine products is not a viable option. However, the burden associated with the application of the full extent of regulatory controls, including the regulation of all pseudoephedrine products, a threshold of zero (whereby records would be required for all transactions regardless of size), and the imposition of a registration requirement on all retailers, would produce an excessive burden on legitimate industry. Given the potentially large impact of such regulatory action, the DEA sought to impose less stringent regulatory requirements so as not to adversely impact legitimate businesses.

In the proposed regulation published in October of 1995, the DEA documented that it had 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 Controlled Substances Act (CSA) chemical regulatory provisions. However, in recognizing the need to limit the regulatory impact on handlers of pseudoephedrine products to a level adequate to prevent the large scale diversion of these products of clandestine use, the DEA has taken significant steps to reduce or eliminate the controls on retailers who sell these pseudoephedrine products of legitimate consumers.

First, given the large number of retail distributors who handle these products in the United States, the DEA has provided a waiver from registration for these distributors. Thus, the 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 firms which would become subject to regulatory controls as a result of this rule.

Secondly, the DEA has limited controls to a specific group of products which have been demonstrated to be most readily used for illicit purposes. This approach provides effective protection against diversion while minimizing the burden on industry. Thirdly, the *proposed* regulations allowed for the purchase and sale of up to a 120 day supply of pseudoephedrine for personal legitimate medical use in a single transaction, without the application of regulatory requirements. Based on comments, in the final rule the DEA doubled the amount to a 244 day supply (976 pseudoephedrine 60 mg dosage units) in a single transaction. Despite concerns that traffickers may exploit this increased threshold, DEA allowed the increase to ensure continued public access to the products for personal legitimate medical use at the retail level. A secondary benefit of this threshold is the fact that many retail outlets do not stock such quantities of pseudoephedrine products, thus obviating concerns regarding their regulation.

Prior to writing the proposed regulation, the DEA 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 met with the Nonprescription Drug Manufacturers Association (NDMA) regarding the U.S. pseudoephedrine market 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 size ranging from 10 to 60 solid dosage units per package. In an effort to reduce the impact upon those who sell and purchase pseudoephedrine products at the retail level, the DEA established a threshold that was well above the standard package size manufactured by NDMA members and distributed by retail distributors. The threshold of 48.0 grams pseudoephedrine base is equivalent to 976 pseudoephedrine hydrochloride 60 mg dosage units.

To further quantify the potential impact of the regulations the DEA has obtained data from the U.S. Bureau of the Census, 1992 Census of Retail Trade. This data documents the number of retail trade establishments based upon Standard Industrial Classification (SIC). This data documents a total of 552,000 potential retailers of pseudoephedrine (to include 63,000 General Merchandise Stores SIC Code 53, 278,000 Food Stores SIC Code 54, 120,000 Gas Service Stations SIC Code 554, 51,000 Drug Stores and Proprietary Stores SIC Code 591 and 40,000 Liquor Stores SIC Code 592).

In addition the DEA has obtained data from the U.S. Department of Agriculture, Economic Research Service, Food Marketing Review which breaks down the number of retail food stores by category for 1993. Of the 249,600 retail food stores documented, 49,500 are classified as convenience stores and 89,800 as Superettes (defined as being primarily self-service in operation, selling a wide variety of food and non-food products with annual sales below $2.5 million.) In addition, the data documents 3,100 Warehouse Stores (which are defined as containing limited product variety and fewer services, while incorporating case lot stocking and shelving practices) and 500 Superwarehouse Retail Outlets (defined as larger warehouses that offer expanded product variety.)

Convenience Stores appear not to even shelf threshold quantities of pseudoephedrine. Such entities which do not stock a threshold quantity and therefore would not exceed the threshold quantities in a single transaction, would not be impacted by these regulations. The 3,600 Warehouse and Superwarehouse outlets, however, may choose to distribute above threshold quantities and therefore would not meet the definition of ''retail distributor''. These entities would therefore be required to register with the DEA and maintain a record of only those transactions which exceed the threshold of 48.0 grams pseudoephedrine base.

Additionally, the National Association of Chain Drug Stores (NACDS) noted point of sale scanning as a possible way to monitor threshold quantities of regulated product in a single transaction. The DEA has obtained data on the percent of Supermarkets having point of sale scanning checkouts. A 1993 study performed by the Maclean Hunter Media, Inc., Stamford, CT, 61st Annual Report of the Grocery Industry indicated that approximately 85 percent of independent and chain supermarkets had scanning checkouts. The percent of Supermarkets having this capability was up from 71 percent in 1990. NACDS's suggestion, therefore, appears to be applicable to the Supermarket industry as well.

The primary impact of the 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. 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 (Title 21 Code of Federal Regulations 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 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 several 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. These various industry and professional groups contacted by the DEA were unable to quantify the number of these firms operating in the U.S. or identify a professional association which represents these business entities. However, in the instance where a state was able to identify the number of firms licensed to distribute drug products into that state, the number of firms was not large, (e.g. As stated in the proposed rule, 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.)

Conclusion

The DEA has substantially limited the impact the regulations will have on pseudoephedrine handlers. The requirements have been designed to ensure that the vast majority of retailers of pseudoephedrine will not be subject to regulation. Retail distributors will not be required to register or maintain records unless they engage in

transactions involving a limited group of pseudoephedrine products in quantities that exceed a 244 day supply in a single transaction. Most retail distributors do not engage in such transactions and therefore will not be subject to these regulations.

The proposed and final rule, in conjunction with this appendix document the various provisions which were specifically provided in order to minimize the impact on small businesses. These provisions were the result of a reasoned analysis of the potential impact of implementation of the full extent of CSA regulations on the affected industry and small businesses in particular. In providing for these special provisions, DEA gave special care and consideration to industry concerns and given these provisions, ensured that these regulations ''will not have significant impact on a substantial number of small entities''.

Dated: July 30, 1996.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 96–19846 Filed 8–6–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31 and 602

[TD 8664]

RIN 1545–AL99

Information Reporting and Backup Withholding; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations [TD 8664] which were published in the Federal Register on Monday, April 22, 1996 (61 FR 17572). The final regulations provide rules regarding the reporting on Form 1042–S of certain bank deposit interest paid with respect to a United States bank account to an individual who is a nonresident alien of the United States and a resident of Canada.

EFFECTIVE DATE: January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Teresa Burridge Hughes, (202) 622–3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations which are the subject of these corrections are under sections 3406 and 6049 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 8664) contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of final regulations (TD 8664), which are the subject of FR Doc. 96–9456 is corrected as follows:

1. On page 17572, column 3, in the preamble following the paragraph heading ''Paperwork Reduction Act'', the first line of the column, the language ''Washington DC 20224, and the Office of'' is corrected to read ''Washington, DC 20224, and the Office of''.

2. On page 17573, column 1, in the preamble following the paragraph heading ''*B. Comments on Canadian Reporting Provisions*'', the third paragraph, line 5, the language ''the Form 1042–S to be the transmittal'' is corrected to read ''the Form 1042 to be the transmittal''.

PART 1—[CORRECTED]

3. On page 17573, column 2, in the authority citation, line 2, the language ''Sections 1.6049–4 also issued under 26'' is corrected to read ''Section 1.6049–4 also issued under 26''.

§ 1.6049–6 [Corrected]

4. On page 17574, column 1, § 1.6049–6(e)(4), the fourth line from the bottom of the paragraph, the language ''information on the Form is being'' is corrected to read ''information on the form is being''.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 96–20125 Filed 8–6–96; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 110

[CGD07–96–017]

RIN 2115–AA98

Anchorage Areas; Ashley River, Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing two new anchorage areas in the Ashley River, Charleston, South Carolina. Due to pending construction of two 1000 ft piers at the George M. Lockwood Municipal Marina, in Charleston, the current anchorage in 33 CFR 110.72d will not be available for anchoring recreational vessels. The Municipal Marina has received a construction permit to build the piers from the U.S. Army Corps of Engineers. The new anchorages are replacing the one described in 33 CFR 110.72d. The new anchorages are across the Ashley River from the current anchorage and though not designated as Federal anchorages, they are already widely used by recreational vessels as overflow from the current anchorage.

DATES: September 6, 1996.

ADDRESSES: Requests for further information should be mailed to the Captain of the Port Charleston, Marine Safety Office Charleston, 196 Tradd Street, South Carolina 29401–1899.

FOR FURTHER INFORMATION CONTACT: CWO4 R.M. Webber, Project Officer, Marine Safety Office Charleston, South Carolina, Tel: (803) 724–7690.

SUPPLEMENTARY INFORMATION:

Regulatory History

On April 23, 1996, the Coast Guard published a notice of proposed rulemaking entitled ''Special Anchorage Areas; Ashley River, Charleston, SC'' (CGD07–96–017) in the Federal Register (61 FR 17861). The comment period ended June 24, 1996. The Coast Guard received 11 comments during the proposed rulemaking period. Eight letters of no objection and three letters in favor of the new anchorages were received. The letters of no objection verified that the anchorages would not impact the environment, historic sites, fisheries or navigation. A public hearing was not requested and one was not held.

Discussion of Regulations

The City Marina Company and the City of Charleston have received a U.S. Army Corps of Engineers permit to build two 1000 foot piers on the south side of the Municipal Marina. Those piers will cross an existing anchorage eliminating most of the anchorages within that area that have over six feet of water at mean low water. As the existing anchorage is extensively used by recreational vessels, the new anchorage areas will accommodate vessels that will be displaced when the new piers are built. There has been considerable public interest in establishing new anchorages to replace the existing anchorage since the marina plans were published in the local newspaper. The new anchorages are already being used by recreational vessels as overflow from the existing anchorage. To date, no problems have