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Robert E. Maher, Jr.,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 03-1813 Filed 1-27-03; 8:45 am]

BILLING CODE 4410-15-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 21, 2002, Bristol-Myers Squibb Pharma Company, 1000 Stewart Avenue, Garden City, New York 11530, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Oxycodone (9143)	II
Hydrocodone (9193)	II
Oxymorphone (9652)	II

The firm plans to manufacture the listed controlled substances to make finished products.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representatives (CCR), and must be filed no later than (60 days from publication).

Dated: January 6, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-1914 Filed 1-27-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated June 24, 2002, and published in the **Federal Register** on July 10, 2002, (67 FR 45764), Cayman Chemical Company, 1180 East Ellsworth Road, Ann Arbor, Michigan 48108, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of tetrahydrocannabinols (7370), a basic class of controlled substance listed in Schedule I.

The firm plans to manufacture tetrahydrocannabinols for sale to their customers.

No comments or objections have been received. DEA has considered the factors in Title 21, U.S.C. 823(a) and determined that the registration of Cayman Chemical Company to manufacture the listed controlled substance is consistent with the public interest at this time. DEA has investigated Cayman Chemical Company on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security system, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: January 6, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-1916 Filed 1-27-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

MDI Pharmaceuticals Revocation of Registration

On September 24, 2001, the Administrator of the Drug Enforcement Administration (DEA), issued an Order to Show Cause and Immediate Suspension of Registration to MDI Pharmaceuticals (MDI) located in Dillon, Montana. MDI was notified of a preliminary finding that pursuant to evidence set forth therein, it was responsible for, inter alia, the diversion of large quantities of list I chemicals into other than legitimate channels. Based on his preliminary findings, and pursuant to 21 U.S.C. 824(d) and 21 CFR 1309.44(a), as well as the authority granted under 21 CFR 0.100, the Administrator ordered the immediate suspension of MDI's DEA Certificate of Registration, 004629IEY, as a distributor of list I chemicals, effective immediately. The suspension was to remain in effect until a final determination was reached in these proceedings.

The Order to Show Cause and Immediate Suspension further informed MDI of an opportunity to request a hearing to show cause as to why DEA should not revoke its DEA Certificate of Registration, and deny any pending applications for renewal or modification of that registration for reason that such registration is inconsistent with the public interest, as determined by 21 U.S.C. 823(h). MDI was also notified that should no request for hearing be filed within 30 days, its right to a hearing would be deemed waived.

On September 26, 2001, a copy of the Order to Show Cause and Immediate Suspension was served upon MDI's owners by DEA Diversion Investigators. DEA has not received a request for hearing or any other reply from MDI or anyone purporting to represent the firm in this matter. Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that MDI is deemed to have waived its hearing right. After considering material from the investigative file in this matter, the Deputy Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds as follows: list I chemicals are those that may be used in the manufacture of a controlled substance in violation of the

Controlled Substances Act, 21 U.S.C. 801(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals that are commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a growing problem in the United States.

A "regulated person" is one who manufactures, distributes, imports, or exports inter alia a listed chemical. 21 U.S.C. 802(38). A "regulated transaction" is inter alia, a distribution, receipt, sale, importation, or exportation of a threshold amount of a listed chemical. 21 U.S.C. 802(39). The Deputy Administrator finds all parties mentioned herein to be regulated persons, and all transactions mentioned herein to regulated transactions, unless otherwise noted.

The Deputy Administrator finds that on June 23, 1999, Isabelle DeLuce (Ms. DeLuce) submitted an application on behalf of MDI for registration with DEA as a distributor of list I chemicals. At the time of the submission of its application, MDI was a distributor of various non-chemical products such as vitamins, herbal products and novelty items. MDI was and is operated by Ms. DeLuce and her husband Michael Uzan (Mr. Uzan).

On October 27, 1999, DEA Diversion Investigators conducted an on-site pre-registration interview of Ms. DeLuce and Mr. Uzan at MDI's proposed registered location. During the interview, investigators warned MDI's owners about the diversion of ephedrine and pseudoephedrine to the illicit production of methamphetamine. The investigators also discussed DEA regulations pertaining to list I chemicals. Ms. DeLuce and Mr. Uzan informed the investigators that they understood the regulations and would comply with all laws pertaining to listed chemicals. Ms. DeLuce also informed investigators that she anticipated that listed chemicals would comprise only 20% of MDI's sales and that these products would be sold to convenience stores and gas stations located only in the State of Montana. Shortly thereafter, MDI was issued a DEA registration as a list I chemical distributor for ephedrine, phenylpropanolamine and pseudoephedrine.

The Deputy Administrator finds that MDI has purchased listed chemicals from a DEA registrant that was the subject of a criminal investigation involving the mishandling of these products. A review of the investigative file reveals that on August 3, 2000, a

Federal search warrant was executed at Wholesale Outlet at its location in Beaumont, Texas. At the time the warrant was executed, Wholesale Outlet was a DEA-registered distributor of list I chemicals. The issuance of the search warrant arose from an ongoing DEA investigation into Wholesale Outlet's listed chemical handling practices. Mediplus Innovations; Suspension of Shipments, 67 FR 41256, 41259 (2002). During the execution of the search warrant, law enforcement officers recovered, among other things, numerous invoices reflecting MDI's purchases of various products from Wholesale Outlet. Of note was MDI's purchase of \$15,840 worth of single entity "Twin Pseudo" brand pseudoephedrine, 60 mg. in 120-count bottles.

Effective May 30, 2002, the Deputy Administrator sustained DEA's suspension of listed chemical shipments imported by a DEA registered importer and destined for sale to Wholesale Outlet. Mediplus at 41256, 41264. Among the reasons cited for sustaining the suspensions was the pending criminal investigation involving Wholesale Outlet, including allegations of suspected misconduct in the handling of list I chemicals, as well as a DEA audit which revealed Wholesale Outlet's failure to account for listed chemicals that it purchased, in violation of 21 U.S.C. 830(a) and 842(a)(10) and 21 CFR 1310.03 and 1310.06. Mediplus at 41263–64. Moreover, the Deputy Administrator found in sustaining the suspensions that psuedoephedrine products distributed by Wholesale Outlet (the same products purchased by MDI from the firm) were found at various clandestine locations throughout the United States and used in the illicit manufacture of methamphetamine.

On August 17, 2000, a DEA Diversion Investigator requested that Ms. DeLuce provide a current customer/supplier list for listed chemicals. Ms. DeLuce informed the investigator that all but two of MDI's 72 customers were located in Nevada, with the majority conducting business in the greater Las Vegas. After providing the requested list of suppliers, Ms. DeLuce stated that MDI purchased 50 to 70 cases of pseudoephedrine, 60 mg., in 120-count bottles, and twenty-two cases of pseudoephedrine, 60 mg. in 60-count bottles on a monthly basis.

The Deputy Administrator's review of the investigative file further reveals that on or about November 30, 2000, Ms. DeLuce and Mr. Uzan were stopped in their automobile by the Las Vegas Police Department and issued a traffic citation. At the time of the traffic stop, the police

officer noticed several cases of pseudoephedrine in the back seat of the vehicle. Ms. DeLuce and Mr. Uzan volunteered that they were distributing or selling pseudoephedrine to local businesses. On a subsequent occasion, Ms. DeLuce was again stopped in her vehicle by law enforcement officers while transporting quantities of pseudoephedrine. During this traffic stop, Ms. DeLuce provided a copy of her DEA registration and informed law enforcement officers that she was aware that pseudoephedrine could be diverted to the illicit manufacture of methamphetamine. During this traffic stop, Ms. DeLuce told the officers that she limited her sales to just one case per customer and that she sold pseudoephedrine to 50 clients about once a month in the greater Las Vegas area because she could not find enough customers in Montana.

Pursuant to 21 CFR 1310.05(a)(1) DEA registrants are required to notify DEA in the event of any regulated transactions involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that indicates that the listed chemical may be used unlawfully. The Deputy Administrator finds that the manner in which Ms. DeLuce and Mr. Uzan transported listed chemicals products in their automobile created a climate for diversion. Therefore, its failure to notify DEA of the uncommon means of transporting a listed chemical results in a finding that MDI, through the actions of its owners, was in violation of section 1310.05.

On April 15, 2001, pursuant to an administrative subpoena, MDI produced its records for the purchase of pseudoephedrine between March 2000 and October 2000. These records revealed that MDI purchased 106,563 bottles of pseudoephedrine valued at \$342,758.00 from four (4) different suppliers over that time period.

MDI also produced its customer list for DEA inspection. A majority of the customers were located in Las Vegas, Nevada, and consisted primarily of gas stations, smoke shops, mini marts and other types of convenience stores. Included among MDI's list of customers was Mike's Smoke Shop, located at 2923 North Avenue in Grand Junction, Colorado. This establishment was owned by Mike Yako (Mr. Yako). During a follow-up investigation on February 13, 2001, DEA special agents discovered that Mike's Smoke Shop had moved to its business location around July 2000 but was evicted from that location in either August or September 2000 for non-payment of rent. Further investigation revealed that during the

time this establishment conducted business, it maintained very little inventory.

A subsequent review of MDI's sales records revealed that from July 31 to November 16, 2000, the firm sold to Mike's Smoke Shop (2923 North Avenue location) approximately 65,650 tablets of pseudoephedrine. During a period of just under three months, MDI distributed an average of over 21,800 tablets per month to this small retailer of tobacco products. Many of the customer receipt documents for these transactions were signed by "M. Yako" or "S. Issa." MDI continued its sale of pseudoephedrine products to Mike's Smoke Shop even after that establishment had closed. Many of these transactions took place within a week of one another. Given the nature of this purported business, the distribution of pseudoephedrine to this establishment was apparently in excess of legitimate demand. The Deputy Administrator finds that MDI failed to report to DEA the sale of an extraordinary quantity of listed chemicals and to verify the existence and validity of a business entity ordering listed chemicals, as required by 21 CFR 1310.05(a) and 1310.07. Furthermore, MDI distributed a listed chemical to this establishment knowing or having reasonable cause to believe that the listed chemical would be used to manufacture illicit methamphetamine in violation of 21 U.S.C. 841(c)(2) (2001).

On February 13, 2001, DEA special agents went to a second establishment under the name of Mike's Smoke Shop, located at 1010 ½ N. 5th St., Grand Junction, Colorado, also owned by Mr. Yako. While signs posted outside the establishment listed hours of operation, it appeared that the business had not been open for some time, DEA agents observed mail lying on the floor inside the door covered by dirt.

Nevertheless, a subsequent review of sales records revealed that between August 9, 2000, and April 18, 2001, MDI sold 3312 bottles of 120-count 60 mg. (397,400 tablets) pseudoephedrine to Mike's Smoke Shop at its 1010 ½ North 5th Street location. During this eight-month period, MDI sold an average of 414 bottles or 49,680 tablets per month this small, retail smoke shop. As with the previous Mike's Smoke Shop location, many of the customer receipt documents for these transactions were signed by "M. Yako" or "S. Issa." Given the nature of this purported business, the distribution of pseudoephedrine to this establishment was apparently in excess of legitimate demand. MDI again failed to report to DEA the sale of an extraordinary quantity of listed

chemicals and to verify the existence and validity of a business entity ordering listed chemicals, as required by 21 CFR 1310.05(a) and 1310.07. MDI also distributed a listed chemical to this establishment knowing or having reasonable cause to believe that the listed chemical would be used to manufacture illicit methamphetamine in violation of 21 U.S.C. 841(c)(2) (2001).

MDI also listed as a customer Paradise Smoker, also located in Grand Junction Colorado, and purportedly owned by an individual by the name of Samer Issa. When DEA special agents sought to verify the existence of the business, they were unable to locate it. Nevertheless, a review of MDI's shipment records revealed that between August 10, 2000 and November 16, 2001, the firm sold approximately 190,080 pseudoephedrine tablets to this small retailer of tobacco products. As with the Mike's Smoke Shop locations, many of the customer receipts were signed on behalf of Paradise Smoker by "M. Yako" or "S. Issa." Given the nature of this purported business, the distribution of pseudoephedrine to this establishment was far in excess of legitimate demand. Therefore, with respect to regulated transactions involving Paradise Smoker, the Deputy Administrator finds that MDI failed to report to DEA the sale of an extraordinary quantity of listed chemicals and to verify the existence and validity of a business entity ordering listed chemicals, as required by 21 CFR 1310.05(a) and 1310.07. MDI also distributed a listed chemical to this establishment knowing or having reasonable cause to believe that the listed chemical would be used to manufacture illicit methamphetamine in violation of 21 U.S.C. 841(c)(2)(2001).

On February 13, 2001, DEA Special Agents interviewed an employee of one of MDI's retail customers, Special Smoke Shop of Delta, Colorado. This small retailer of tobacco products was purportedly owned by Suhail Issa. The employee informed investigators that tobacco products were the only products sold in the store that its owner ordered boxes of goods, which were paid for by money orders. The employee also revealed that the inventory of these boxes was never sold from the store; rather, the owner removed these boxes as soon as they were delivered to the store.

DEA's review of sales records revealed that MDI sold approximately 3,600 bottles of 120-count 60 mg. (432,000 tablets) pseudoephedrine to Special Smoke Shop between August 10, 2000 and April 18, 2001. During this eight-month period, MDI sold an average of 450 bottles (or 54,000 tablets)

per month to this establishment. Again, several of the customer receipt documents showed that they were signed on behalf of this customer by "M. Yako" and "S. Issa." Given the nature of this purported business, MDI's distribution of pseudoephedrine to this establishment was far in excess of legitimate demand. Therefore, with respect to regulated transactions involving Special Smoke Shop, the Deputy Administrator finds that MDI failed to report to DEA the sale of an extraordinary quantity of listed chemicals and to verify the existence and validity of a business entity ordering listed chemicals, as required by 21 CFR 1310.05(a) and 1310.07. MDI also distributed a listed chemical to this establishment knowing or having reasonable cause to believe that the listed chemical would be used to manufacture illicit methamphetamine in violation of 21 U.S.C. 841(c)(2)(2001).

Shortly thereafter, a DEA Special Agent visited another MDI retail customer, Special Smoke (an apparent name variation of "Special Smoke Shop"), located in Fruita, Colorado. Special Smoke was also a retailer of tobacco products and purportedly owned by Suhail Issa. The Special Agent, posing as a customer, noticed that two bottles of pseudoephedrine were displayed in the store along with a sign that read, "Limit three (3) per purchase." A subsequent review of MDI sales records revealed that between January 4, 2000 and April 13, 2001, the company sold 3312 bottles of 120-count 60 mg. (397,440 tablets) pseudoephedrine to Special Smoke. Some of these transactions took place within two to five days of one another.

In addition, several of the customer receipt documents showed that they were signed by "M. Yako" and "S. Issa" as well as by other persons associated with the Mike's Smoke Shop locations, Paradise Smoke and Special Smoke Shop. Given the nature of this purported business, the distribution of pseudoephedrine to this establishment was far in excess of legitimate demand. Therefore, with respect to regulated transactions involving Special Smoke Shop, the Deputy Administrator finds that MDI failed to report to DEA the sale of an extraordinary quantity of listed chemicals and to verify the existence and validity of a business entity ordering listed chemicals, as required by 21 CFR 1310.05(a) and 1310.07. MDI also distributed a sited chemical knowing or having reasonable cause to believe that the listed chemical would be used to manufacture illicit methamphetamine in violation of 21 U.S.C. 841(c)(2) (2001).

The Deputy Administrator's review of the investigative file reveals that pseudoephedrine products distributed by MDI have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in the possession of individuals apparently involved in the illicit manufacture of methamphetamine. On February 20, 2001, the Las Vegas Metropolitan Police Department (LVMPD) arrested three individuals in an apartment complex in response to a small fire in their unit. At the time of the arrest, LVMPD officers discovered a methamphetamine laboratory inside the apartment. Numerous items associated with the illicit manufacture of methamphetamine were also recovered from the apartment, including three empty 120-count bottles of MDI brand 60mg. pseudoephedrine tablets.

On April 4, 2001, two individuals were arrested by the LVMPD when a search of a residence revealed items associated with the illicit manufacture of methamphetamine, including twenty 120-count bottles of MDI brand 60mg. pseudoephedrine tablets. The investigative file further reveals that from April 16 to August 8, 2001, there were approximately thirteen additional seizures of MDI brand pseudoephedrine products at various clandestine laboratory settings. These seizures occurred primarily in the Las Vegas area, as well as at locations in Colorado and California.

The Deputy Administrator finds that on February 22, 2001, the Federal Express office in St. George, Utah received six cases of pseudoephedrine which were shipped by MDI purportedly to six different business locations; however, all six cases were picked up by one person in a vehicle registered to Samer Issa. Business records for the city of St. George had no current information for three of the business entities. Business licenses for the other three businesses were issued to Marogy Marogy (later determined to be Samer Issa's brother-in-law), Mike Yako and a "Suhel Aesa."

On March 14, 2001, a DEA Task Force Officer (TFO) acting in an undercover capacity met with Mike Yako at a location in Las Vegas, Nevada to arrange the purchase of a half case of pseudoephedrine. After agreeing to a price for half a case of pseudoephedrine, Mr. Yako was observed by law enforcement officers going into a storage unit, where he later emerged carrying a brown box which he placed in the trunk of his car. Mr. Yako then removed from the car trunk a bottle of MDI brand pseudoephedrine, which he handed to

the TFO. Yako then stated to the TFO that MDI brand "is doing so well" his store put their own labels on the bottles. Mr. Yako then accepted from the undercover TFO \$2,000 cash for 72 bottles of MDI pseudoephedrine tablets. During an April 3, 2001 undercover operation, the TFO stated his intentions to purchase five cases of pseudoephedrine from Mr. Yako in the near future, to which Mr. Yako replied, "no problem."

On March 18, 2001, a Colorado State Trooper made a traffic stop of a vehicle driven by Suhail Issa, who was accompanied by Mike Yako. Mr. Yako informed the trooper that he was visiting Colorado to oversee "smoke shop" stores that he owned in the state. He further stated that the two were on their way to Las Vegas, and had planned a temporary stop in Fruita, Colorado, to purchase gasoline for the vehicle they were driving. After obtaining permission to search the vehicle, the trooper found three boxes of pseudoephedrine. Contained within the three boxes were Federal Express shipping labels dated April 16, 2001, and invoices from MDI to Special Smoke locations in Fruita, Grand Junction, and Delta, Colorado. Mike Yako explained that the three boxes were "stuff for my business." The trooper seized the three boxes, but did not arrest the two passengers.

On May 24, 2001, Diversion Investigators visited Ms. DeLuce and Mr. Uzan at their residence in Dillon, Montana. DEA personnel discussed with Ms. DeLuce and Mr. Uzan information regarding MDI pseudoephedrine products that were found at various clandestine methamphetamine settings. In response, Ms. DeLuce explained that she limits her customers to only two cases per month and that she sells pseudoephedrine in bottles rather than in blister packs because her customers prefer bottles. She also stated that she had 137 customers, most of whom were located in Las Vegas.

DEA also discussed with Ms. DeLuce the above referenced traffic stop of Suhail Issa and Mike Yako by the Colorado State Police. Ms. DeLuce acknowledged that these individuals were customers of MDI, and that she had been informed of the traffic stop. Ms. DeLuce also stated that she thought the two customers fabricated the story about the seizure in order to obtain more pseudoephedrine from MDI. Ms. DeLuce further added that despite her suspicions regarding the circumstances of traffic stop and the fact that the two customers were transporting pseudoephedrine products in the trunk

of an automobile, she failed to report these matters to DEA as a suspicious transaction. Ms. DeLuce explained that she did not report the incident because she believed DEA was already aware of the seizure.

Despite her representations to DEA personnel, the Deputy Administrator finds that information previously communicated to Ms. DeLuce regarding the traffic stop of her customers, and their being found in possession of caseload quantities of pseudoephedrine which were later seized, should have raised red flags that these products were being diverted to illicit uses. Ms. DeLuce admitted that the circumstances surrounding the traffic stop were suspicious. As a registrant entrusted with securing a product that is frequently diverted to illicit uses, MDI was required to notify DEA of the suspicious circumstances surrounding the traffic stop of its customers pursuant to 21 CFR 1310.05(a).

The investigative file further reveals that Ms. DeLuce and Mr. Uzan informed DEA personnel that because of the traffic stop involving Mister Issa and Yako, MDI suspended all sales of its products to any establishment in which these customers were affiliated. They further indicated that the "smoke shop" stores operated by Issa and Yako in Colorado had closed. However, DEA subsequently obtained Federal Express records which showed that on at least thirty-nine separate occasions following the traffic stop by the Colorado State Police, MDI continued its shipment of caseload quantities of pseudoephedrine to business establishments operate by Suhail Issa and/or Mike Yako. Included among these transactions were numerous shipments of listed chemicals to "smoke shops" in Colorado. At least three of the transactions occurred after Ms. DeLuce assured DEA personnel that MDI no longer sold listed chemicals to these customers.

A further review of the investigative file reveals that MDI shipped pseudoephedrine products to a customer in St. George, Utah. Ms. DeLuce informed DEA personnel that MDI later determined that the customer was operating from a fictitious address. However, Ms. DeLuce admitted that MDI failed to report this suspicious transaction, as required by 21 CFR 1310.05(a)(1)

The Administrator of DEA made a preliminary finding that MDI has been responsible for the diversion of large quantities of pseudoephedrine into other than legitimate channels, in violation of 21 U.S.C. 830(b)(3) and 841(c)(2). The Administrator also found that despite MDI's awareness of

problems associated with pseudoephedrine diversion, and laws pertaining to listed chemicals, the firm had continually and consistently violated DEA laws pertaining listed chemicals, thus resulting in large quantities of pseudoephedrine being diverted to the illicit production of methamphetamine. Therefore, pursuant to 21 U.S.C. 824(d), the Administrator of DEA issued an immediate suspension of MDI's DEA Certificate of Registration.

As noted above, on September 26, 2001, DEA Diversion Investigators served the Order to Show Cause and Immediate Suspension on Ms. DeLuce at her residence in Dillon, Montana. On that same date, Ms. DeLuce and Mr. Uzan were arrested by DEA Special Agents and charged with offenses related to the unlawful distribution and possession of listed chemicals. At the time of her arrest, Ms. DeLuce agreed to answer questions regarding her sale of listed chemicals and customers who purchased these products from MDI.

Ms. DeLuce informed DEA agents that she knew her products were being sold "on the street." She further admitted that she knew Samer and Suhail Issa, as well as Fehmi Awad (Mr. Awad) were probably abusing pseudoephedrine (*i.e.*, "selling too much"). Ms. DeLuce further stated that she knew Mr. Awad was picking up pseudoephedrine products at four different stores, and Samer Issa was selling the products to illicit methamphetamine manufacturers for about a year. She further admitted knowing that certain customer accounts in Utah and Colorado where MDI shipped pseudoephedrine products were fronts for Samer Issa. Samer Issa reportedly set these stores up in the name of his brother as well as in the names of others.

Ms. DeLuce further informed to DEA agents that she knew pseudoephedrine was a "hot item" in Las Vegas because of the methamphetamine problem, and that 97% of MDI's customers were in that area. She estimated that her company made a profit from the sale of pseudoephedrine of between \$700,000 to \$800,000 a year at approximately \$1,000 per case. Ms. DeLuce also disclosed that Samer Issa informed her that a case of pseudoephedrine sold for approximately \$4000.00 on the street. Despite suspicions that her customers were selling MDI pseudoephedrine products to illicit methamphetamine cooks, Ms. DeLuce said that she essentially closed her eyes and ignored the actions of her customers. She further admitted that it was hard to stop selling a product that sold for \$1,000 a case.

The Deputy Administrator's review of the investigative file reveals that on

October 10, 2001, a Federal Grand Jury in the District of Nevada issued a twenty-nine count indictment against Ms. DeLuce, Mr. Uzan, as well as Samer and Suhail Issa, Fehmi Awad, Mike Yako, and two additional individuals. Among the charged offenses were conspiracy to distribute a listed chemical with knowledge or reasonable cause to believe it would be used to manufacture a controlled substance in violation of 21 U.S.C. 846 and 841(c)(2); possession of a listed chemical in violation of 21 U.S.C. 841(c)(2) and 18 U.S.C. 2; and unlawful use of a communication facility, namely telephones and telephone wires, in causing and facilitating the commission of a conspiracy, in violation of 21 U.S.C. 843(b). These matters are currently pending resolution.

The Deputy Administrator finds that the above-cited evidence provides ample grounds for an immediate suspension pursuant to 21 U.S.C. 824(d). These grounds also provide the basis for the revocation of MDI's DEA Certificate of Registration.

Pursuant to 21 U.S.C. 824(a), the Deputy Administrator may revoke a registration to distribute list I chemicals upon a finding that the registrant has committed such acts as would render his registration under section 823 inconsistent with the public interest as determined under that section. Pursuant to 21 U.S.C. 823(h), the following factors are considered in determining the public interest:

- (1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) Compliance with applicable Federal, State, and local law;
- (3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) Any past experience in the manufacture and distribution of chemicals; and
- (5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or combination of factors of factors, and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See, e.g.* Energy Outlet, 64 FR 14269 (1999). *See also* Henry J. Schwartz, Jr., M.D. 54 FR 16422 (1989).

With respect to factor one, maintenance of effective controls against diversion, the Deputy Administrator finds substantial evidence in the investigative file that MDI, through its owners Isabelle DeLuce and Michael Uzan, participated in the unlawful diversion of pseudoephedrine having reasonable cause to believe that it would be used to manufacture illicit methamphetamine. Ms. DeLuce and Mr. Uzan transported bottles of pseudoephedrine in the trunk of their automobile and distributed these products to gas stations, smoke shops, mini marts and other convenience stores in the vicinity of Las Vegas, Nevada, an area known for large numbers of seizures involving clandestine methamphetamine laboratories. DEA previously denied the application of a retail establishment that sought registration as a distributor of list I chemicals when it was found through "past DEA investigations and experience" that the primary source for diversion of listed chemicals in areas where the applicant sought to distribute, specifically in Las Vegas, Nevada, were mini marts and other types of convenience stores. Sinbad Distributing, 67 FR 10232, 10233 (2002). *See e.g.* K.V.M. Enterprises, 67 FR 70968 (2002) (denial of application based in part upon information developed by DEA that the applicant proposed to sell listed chemicals to gas stations, and the fact that these establishments in turn have sold listed chemical products to individuals engaged in the illicit manufacture of methamphetamine).

Factor one is also relevant to MDI's distribution of large quantities of pseudoephedrine products to numerous establishments associated with Mike Yako and Saher Issa, despite knowledge on the part of Ms. DeLuce and Mr. Uzan that these establishments were fronts for obtaining listed chemicals for use in the illicit manufacture of methamphetamine. On numerous occasions, MDI failed to report to DEA the sale of an extraordinary quantity of listed chemicals or verify the existence and validity of a business entity ordering listed chemicals, as required by 21 CFR 1310.05(a) and 1310.07. MDI failed to notify DEA that its customer was stopped by law enforcement authorities, and had cases of pseudoephedrine taken from the trunk of an automobile which was seized. In addition, MDI failed to notify DEA that it had shipped pseudoephedrine products to a customer with a fictitious address.

Regarding factor two, the investigative file reveals that MDI failed to comply with applicable Federal laws by not

reporting the sale of extraordinary quantities of listed chemicals or uncommon method of delivery; verify the existence and validity of business entities; and distributed listed chemicals with knowledge that they were being diverted, as set forth in factor one above. MDI also failed to make required reports of suspicious listed chemical transactions pursuant to 21 U.S.C. 830(b)(1)(A), in that the firm distributed large quantities of pseudoephedrine tablets to smoke shops and other convenience stores in quantities that apparently exceeded legitimate demand for these products.

In addition, MDI's owners were notified by DEA Diversion Investigators of dangers surrounding the diversion of list I chemicals. Ms. DeLuce demonstrated her knowledge of this fact on several occasions, as evidenced by her statement to a law enforcement officer during a traffic stop that she was aware of the illicit uses of pseudoephedrine. Therefore, MDI's distribution of large quantities of pseudoephedrine to smoke shops and convenience stores were in violation of 21 U.S.C. 841(d)(2) (2001), since its owners, by their own admission, knew that these products were being diverted to the illicit manufacture of methamphetamine. *See, e.g.* Ace Wholesale & Trading Co., 67 FR 12574, 12576 (2002).

The Deputy Administrator also finds factor two applicable to MDI's failure to notify DEA of the circumstances surrounding the traffic stop of its customers in the State of Colorado, and the seizure of MDI pseudoephedrine products that were being transported in the customer's automobile. Factor two is also applicable to the criminal indictment by a Federal Grand Jury of Ms. DeLuce, Mr. Uzan, as well as several individuals who purchased pseudoephedrine products from MDI. These charges stem from allegations regarding the unlawful distribution and possession of listed chemicals, and are pending resolution.

Notwithstanding the pending criminal charges facing its owners, with respect to factor three, there is no evidence in the investigative file that MDI, Ms. DeLuce or Mr. Uzan have any prior conviction record under Federal or State laws relating to controlled substances or chemicals.

With respect to factor four, past experience in the manufacture and distribution of chemicals, the Deputy Administrator finds substantial evidence in the investigative file that Ms. DeLuce and Mr. Uzan failed to maintain adequate controls in distributing pseudoephedrine products, and actively participated in the

unlawful trafficking of this listed chemical knowing that it was being diverted to the manufacture of methamphetamine, as set forth above under factors one and two.

With respect to factor five, such other factors relevant to and consistent with the public safety, the Deputy Administrator finds substantial evidence in the investigative file that the owners of MDI cannot be entrusted with the responsibilities inherent in a DEA registration. Ms. DeLuce and Mr. Uzan distributed large quantities of pseudoephedrine to locations not typically associated with large-scale transactions involving these over-the-counter products (*i.e.*, small retailers of tobacco products). DEA's has obtained information that MDI pseudoephedrine products have been found at numerous clandestine settings.

In light of these events, the Deputy Administrator finds it particularly disturbing that MDI's owners were aware that their pseudoephedrine products were being diverted to illicit uses, but chose to ignore this fact, apparently in the interest of financial gain. Ms. DeLuce and Mr. Uzan were so cavalier and reckless in their quest for profit that they shipped caseloads quantities of pseudoephedrine tablets to non-existent business locations. Such conduct on the part of a DEA registrant is unacceptable, and lends further support to the revocation of a DEA Certificate of Registration.

Ms. DeLuce also demonstrated a lack of candor in her dealings with DEA personnel. On May 24, 2001, Ms. DeLuce informed DEA Diversion Investigators that MDI limited its sale of pseudoephedrine to its customers to one case (or 144 bottles containing 120 tablets) per month. However, Ms. DeLuce's statements are not corroborated by DEA's investigative findings:

The investigative file reveals that in October 2000, MDI sold caseload quantities of pseudoephedrine to Mike's Smoke Shop (2923 North Avenue location) on three occasions; in 2000, during the months of September, November and December, MDI sold caseload quantities to Mike's Smoke Shop (1010½ North 5th Street location) on three separate occasions. In March 2001, MDI shipped caseload quantities of pseudoephedrine to that same location on four occasions; in October 2000, MDI sold caseload quantities of pseudoephedrine to Paradise Smoke, Special Smoke Shop and Special Smoke Shop on four separate occasions for each store. MDI also sold caseload quantities of pseudoephedrine to Special Smoke Shop on four occasions in March 2001, including two caseloads

that were sent within two days of one another.

Ms. DeLuce further informed DEA Diversion Investigators that MDI suspended all sales of pseudoephedrine products to any retail establishment affiliated with Suhail Issa and Mike Yako as a result of the aforementioned traffic stop in Colorado. She further represented that the smoke shop establishments operated by Suhail Issa and Mr. Yako in the State of Colorado had closed. Despite Ms. DeLuce's representations, DEA obtained information that MDI continued its sale of pseudoephedrine products to establishments operated by Suhail Issa and Mr. Yako in the State of Colorado following the March 18, 2001, traffic stop. At least three of the transactions took place after Ms. DeLuce provided assurances to DEA personnel that she had discontinued the sale of listed chemicals to Suhail Issa and Mr. Yako.

The Deputy Administrator finds this lack of candor, taken together with the registrant's disregard of laws and regulations pertaining to a DEA registration to distribute listed chemicals, makes questionable MDI and its owner's commitment to the DEA statutory and regulatory requirements designed to protect the public from the diversion of listed chemicals. Seaside Pharmaceutical Co., 67 FR 12580 (2002); Aseel, Incorporated, Wholesale Division, 66 FR 35459 (2001); Terrence E. Murphy, M.D., 61 FR 2841 (1996).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, 0046291EY, previously issued to MDI Pharmaceuticals, be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of said registration be, and they hereby are, denied. This order is effective February 27, 2003.

Dated: January 2, 2003.

John B. Brown, III,
Deputy Administrator.

[FR Doc. 03-1915 Filed 1-27-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacture of Controlled Substances Notice of Registration

By Notice dated June 18, 2002, and published in the **Federal Register** on