significant diversion risks. Review of the APA's definitions of license and licensing reveals that the granting or denial of a manufacturer's registration is a licensing action, not a rulemaking. Courts have frequently distinguished between agency licensing actions and rulemaking proceedings. *See, e.g. Gateway Transp. Co.* v. *United States*, 173 F. Supp. 822, 828 (D.C. Wis. 1959); *Underwater Exotics, Ltd.* v. *Secretary of the Interior*, 1994 U.S. Dist. LEXIS 2262 (1994) Courts have interpreted agency action relating to licensing as not falling within the APA's rulemaking provisions.

DEA has considered the factors in Title 21, United States Code, Section 823 (a) and the objector's arguments, and determined that the registration of the ISP Freetown Fine Chemicals Inc. to manufacture 2,5-Dimethoxyamphetamine is consistent with the public interest at this time. DEA has investigated the firm to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the applicant's physical security systems, verification of the applicants compliance with state and local laws, and review of the firm's background and history.

Under Title 21, Code of Federal Regulations, Section 1301.33b, DEA is not required to limit the number of manufacturers solely because a smaller number is capable of producing an adequate supply provided effective controls against diversion are maintained. DEA has determined that effective controls against diversion will be maintained by ISP Freetown Fine Chemicals Inc.

Therefore, pursuant to 21 U.S.C. Section 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 2,5-Dimethoxyamphetamine is granted.

Dated: October 27, 1999.

John H. King,

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

[FR Doc. 99–28604 Filed 11–1–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98–37]

NVE Pharmaceuticals, Inc.; Denial of Applications

On July 14, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to NVE Pharmaceuticals, Inc. (Respondent), notifying it of an opportunity to show cause as to why DEA should not deny its May 7, 1997 applications for registration as an exporter of List I chemicals pursuant to 21 U.S.C. 958(c) and as a manufacturer for distribution of List I chemicals pursuant to 21 U.S.C. 823(h), for reason that such registration would be inconsistent with the public interest.

Respondent timely filed a request for a hearing on the issues raised by the Order to Show Cause. The hearing was held in Newark, New Jersey on December 3, 1998, before Administrative Law Judge Gail A. Randall. At the hearing, the Government called witnesses to testify and introduced documentary evidence. Respondent introduced documentary evidence, however it did not call any witnesses to testify. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. On June 17, 1999, Judge Randall issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision, recommending that Respondent's applications for registration be denied. Neither party filed exceptions to Judge Randall's Recommended Rulings, Findings of Fact, Conclusions of Law and Decision, and on July 21, 1999, Judge Randall transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, except as specifically noted, the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that Respondent was incorporated in 1986 with Robert Occhifinto as its president. Respondent is a manufacturer and distributor of over-the-counter pharmaceutical products and nutritional vitamins, including diet and exercise supplements. Some of the products that Respondent manufactures and sells contain, in whole or in part, the listed chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (PPA). Respondent employs over 70 individuals, many of whom are extremely handicapped. As early as 1997, Respondent established a position for a ''Regulatory Affairs'' representative who is responsible for ensuring that Respondent complies with regulatory requirements.

Mr. Occhifinto is involved in numerous community and religious activities. He donates his time and personal resources to a variety of causes, and is also responsible for transforming a toxic waste site into a productive business complex.

The Deputy Administrator finds that ephedrine, pseudoephedrine and PPA are all List I chemicals that have legitimate uses, but they can also be used in the illicit manufacture of controlled substances. Ephedrine and pseudoephedrine can be used to manufacture methamphetamine, a Schedule II controlled substance that is a very potent central nervous system stimulant. Abuse of methamphetamine is a growing problem in the United States. The chemicals needed to manufacture methamphetamine are readily accessible at almost any pharmacy or retail store that sells pharmaceutical products. Ephedrine and pseudoephedrine extracted from over-the-counter products is often used in the illicit manufacture of methamphetamine.

In an effort to curb the use of licit chemicals in the illicit manufacture of controlled substances, Congress amended the Controlled Substances Act in 1988 with the passage of the Chemical Diversion and Trafficking Act (CDTA). Pub. L. 100–690, 102 Stat. 4181 (1988). The CDTA required that records and reports be made of certain transactions involving various chemicals. However, products containing ephedrine and pseudoephedrine were exempt from the recordkeeping and reporting requirements because they were approved for marketing under the Federal Food, Drug, and Cosmetic Act. The CDTA also made it illegal to distribute a listed chemical ''knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance * * *.'' *See* 21 U.S.C. 841(d)(2).

In November 1990, the DEA office in San Francisco discovered four 25

kilogram drums of ephedrine hydrochloride with Respondent's labels on them during the course of an investigation of a large scale methamphetamine manufacturing organization. As a result, the DEA office in Newark began an investigation of Respondent. A review of United Parcel Service (UPS) records, revealed that Respondent had been shipping ephedrine to an individual who lived in West Virginia, and later in California.

During the course of its investigation, DEA discovered that a New York chemical supplier shipped ephedrine hydrochloride to Respondent on July 12, 1990. A review of Respondent's shipping invoices indicated that Respondent claims to have shipped 4,000 bottles of 25 milligram ephedrine tablets to the individual in West Virginia on July 13, 1990. A UPS invoice dated July 13, 1990, indicated that four 70 pound packages were shipped from Respondent to the individual in West Virginia.

A DEA investigator compared the incoming bulk shipment from the New York chemical company to Respondent with the outgoing shipment from Respondent to the individual in West Virginia, and concluded that for the amount of bulk ephedrine purchased by Respondent, an insufficient number of ephedrine tablets was being manufactured. Additionally, the recorded weight of the UPS shipment did not correspond with the same shipment as indicated by Respondent's shipping invoice. Each 25 milligram ephedrine tablet actually weighed 85 milligrams due to the binders and fillers holding the tablet together. Therefore, if 4,000 bottles of 25 milligram tablets were shipped to the individual, as indicated on Respondent's shipping invoice, then the weight of the shipment would have been more than 2.5 times the weight of what was actually shipped according to the UPS record.

Later in 1990, a New Jersey chemical company contacted DEA regarding a suspicious order for ephedrine hydrochloride that it had received from Respondent. DEA controlled and monitored the shipment from the New Jersey chemical company to Respondent, then from Respondent to UPS, and finally to California where it was delivered to the individual's residence. About a week later, in early January 1991, UPS advised DEA of an additional shipment from Respondent to an address in California. Once again, DEA controlled and monitored the shipment from Respondent to the individual's residence in California.

Respondent and Mr. Occhifinto ultimately admitted that from March 22, 1990 through January 2, 1991, 22 shipments totaling 2,700 kilograms of bulk ephedrine hydrochloride powder were shipped from Respondent to the individual. DEA confirmed that the product shipped to the individual was bulk hydrochloride powder, and not ephedrine tablets as indicated by Respondent's invoices. At the time of these shipments, records would have been required for the shipment of bulk ephedrine hydrochloride, however, no records were required for the shipment of ephedrine tablets.

During the course of this investigation, DEA learned that in late 1900 Mr. Occhifinto had been arrested in Florida. In August 1991, Mr. Occhifinto was convicted in the United States District Court for the Middle District of Florida of conspiracy to import hashish, conspiracy to possess hashish, importation of hashish and possession of hashish with intent to distribute. The pre-sentencing report introduced into evidence indicates that the hashish that customs officials confiscated from Mr. Occhifinto was given to him, without his knowledge, by a traveling companion, Roland Bossi. Both Mr. Occhifinto and Mr. Bossi confirmed that ''(Mr.) Occhifinto had no knowledge prior to (his arrival at customs) about the contraband that he was carrying.'' The sentencing judge granted Mr. Occhifinto a downward departure from the sentencing guidelines, ''predicated on the (Respondent's) extremely limited involvement in the offense.'' Mr. Occhifinto was fined $200.00 and received probation.

Following DEA's investigation of Respondent, Mr. Occhifinto cooperated extensively with law enforcement personnel. He provided truthful information regarding Respondent's transactions with the individual in California, and never hid any aspects of his dealings with the individual. He also participated in the criminal prosecution of the individual

On December 17, 1991, Mr. Occhifinto entered into a plea agreement with the United States Attorney's Office, District of New Jersey. He pled guilty to one count of money laundering under 21 U.S.C. 1956, stemming from the transactions between Respondent and the individual, and accepted full responsibility for his actions. In the stipulations attached to the plea agreement, Mr. Occhifinto admitted that he ''knew that the funds were the proceeds of unlawful activity involving the manufacture and distribution of controlled substances.''

Mr. Occhifinto continued to cooperate with law enforcement personnel and in September 1995, he entered into a voluntary diversionary agreement with DEA, where he agreed, among other things, to limit his sales of pseudoephedrine and to provide DEA with information regarding Respondent's sales of pseudoephedrine.

On June 4, 1996, as a result of his guilty plea, the United States District Court, District of New Jersey, sentenced Mr. Occhifinto to 18 months incarceration, and ordered him to pay a fine of $50,000.00. Mr. Occhifinto was released from prison on December 30, 1997, and he was placed on three years of supervised release.

In 1993, recognizing, among other things that the use of over-the-counter ephedrine products in the illegal manufacture of methamphetamine was increasing, Congress passed the Domestic Chemical Diversion Control Act (DCDCA). Pub. L. 103–200, 107 Stat. 2333 (1993). The DCDCA removed the exemption from recordkeeping and reporting requirements for single entity ephedrine products. In addition, the DCDCA established a registration system for certain handlers of List I chemicals.

On May 7, 1997, Respondent submitted applications for DEA Certificates of Registration to manufacture and to export ephedrine. By Letter to DEA dated September 9, 1997, Respondent requested a modification of both its May 7, 1997 applications, to include the listed chemicals pseudoephedrine and PPA. Since Mr. Occhifinto was incarcerated at the time that the applications were submitted, another individual, by power of attorney, signed the applications and the September 7, 1997 letter, on behalf of Respondent.

The individual who submitted the applications answered ''Yes'' to the question on the applications which asked:

> Has the applicant ever been convicted of a crime in connection with controlled substances/listed chemicals under State or Federal law, or ever surrendered or had a Federal registration revoked, suspended, restricted or denied, or ever had a State professional license or registration revoked, suspended, denied, restricted or placed on probation?

In addition, he answered ''Yes'' to the question which asked:

> If the applicant is a corporation * * * has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substances/listed chemicals under State or Federal law, or ever surrendered or had a Federal controlled substance or listed chemical registration revoked, suspended, restricted or denied, or ever had a State professional license or

controlled substance or chemical registration revoked, suspended, denied, restricted or placed on probation?

These questions are hereinafter referred to as the liability questions. The applications further stated that if a ''Yes'' answer is provided for either of the liability questions, the applicant should ''include a statement using the space provided on the [reverse side of the application.]'' In addition, the applications stated that for a ''Yes'' answer, the applicant is ''required to submit a statement explaining such response(s).'' However, the applications did not specifically inform the applicant to state the nature of the convictions or to state what type of conviction it was or when it occurred. The following statement was on the reverse of both applications submitted on behalf of Respondent:

1990–1991 I sold ephedrine hydrochloride without filing out the appropriate paperwork.

For the past 7 years NVE has manufactured ephedrine-based products without incident and has cooperated extensively with the DEA on numerous occasions.

The DEA investigator who testified at the hearing does not believe that these responses were adequate, since they do not indicate that the president of Respondent was convicted of a crime in connection with controlled substances or listed chemicals.

DEA conducted its pre-registration investigation of Respondent in August or September of 1997. DEA recommended that Respondent install an alarm system in the area in which listed chemicals were going to be stored. According to the DEA investigator, Respondent installed ''(a) pretty elaborate alarm system.'' Later in the fall of 1997, DEA tested the alarm system and concluded that the physical security at Respondent was adequate.

Since Respondent applied for registration prior to a specific date, it was authorized to continue to manufacture and export List I chemicals until its applications for registration were acted upon by DEA. However, it was only authorized to conduct transactions involving listed chemicals with other registered entities or entities that had timely filed applications for registration. Respondent recognized this limitation on its ability to conduct transactions involving ephedrine hydrochloride, pseudoephedrine and PPA. In a letter to its customers dated September 25, 1997, Respondent's Senior Vice President Ron Bossi stated that ''it is *mandatory* (that Respondent) have a copy of (the customer's) registration application * * * (and Respondent) must receive a copy of (the customer's) approved application as well.''

Respondent regularly sent DEA monthly sales reports for ephedrine, pseudoephedrine and PPA products. A review of these reports revealed that from January 6, 1998 to October 28, 1998, Respondent entered into at least 36 separate transactions involving pseudoephedrine with Select Health, a business located in Oklahoma. Respondent never tried to hide the existence of these sales to Select Health. Since the quantities sold by Respondent to Select Health appeared to be excessive, DEA conducted further investigation. It was determined that Select Health was not registered with DEA to handle listed chemicals, nor did it have an application for registration pending. It was further determined that because almost all of Select Health's business is conducted by mail order, Select Health needed to be registered with DEA.

Although Respondent did disclose its sales to Select Health to DEA, DEA did not inform Respondent that Select Health was not registered. When Respondent independently became aware that Select Health was not registered, Respondent contacted DEA.

After being notified that Select Health had received approximately 3.5 million dosage units of listed chemicals from Respondent, a DEA investigator went to Select Health and met with its owner. The owner informed the investigator that Select Health did not have a DEA registration, nor was she aware that it needed to be registered with DEA. The owner further stated that Respondent never informed her that Select Health needed to be registered with DEA.

In September 1998, DEA seized bottles of 480 tablets of one of Respondent's pseudephedrine products from clandestine laboratories.

Pursuant to 21 U.S.C. 823(h) and 958(c), the Deputy Administrator may deny an application for a DEA Certificate of Registration, if he determines that granting the registration would be inconsistent with the public interest. Section 823(h) requires that the following factors be considered in determining the public interest.

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) Compliance by the applicant with applicable Federal, State, and local law;

(3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) Any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) Such other factors as are relevant to and consistent with the public health and safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may properly rely on any one or a combination of factors, and may give each factor the weight he deems appropriate in determining whether any application for registration should be denied *See, e.g. Energy Outlet,!* 64 FR 14269 (1999), *see also Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989).

As a preliminary matter, DEA has consistently held that a retail store operates under the control of its owners, stockholders, or other employees. therefore, the conduct of these individuals is relevant in evaluating the fitness of an applicant or registrant for registration. *See, e.g., Energy Outlet,* 64 FR 14 14269 (1999); *Rick's Pharmacy,* 62 FR 42595 (1997); *Big T Pharmacy, Inc.,* 47 FR 51830 (1982). Since, Robert Occhifinto is the president of Respondent, his conduct is relevant in determining whether or not to grant Respondent's applications for registration.

Regarding factor one and Respondent's maintenance of effective controls against the diversion of listed chemicals, it is undisputed that the alarm system and physical security at Respondent is adequate to protect against the diversion of listed chemicals. However as the Government argued, not only did Respondent not maintain effective controls against diversion in its transactions with the individual from West Virginia and then California, it actively engaged in diversion. It shipped ephedrine to the individual on 22 separate occasions knowing that the ephedrine would be used in the illicit manufacture of methamphetamine. Respondent intentionally falsified its invoices to conceal the actual contents of the shipments to avoid DEA's recordkeeping requirements.

In addition, Respondent engaged in at least 36 transactions involving listed chemicals with Select Health, a company not registered with DEA to handle listed chemicals. Pursuant to 21 CFR 1310.07(a), it was Respondent's responsibility to properly identify the other party to a transaction by verifying the identity or registration status of the other party. Here there is no evidence in the record that Respondent attempted to ascertain the registration status of Select Health. As a result, Respondent shipped approximately 3.5 million dosage units

of listed chemicals to a company not authorized by DEA to handle the chemical. Respondent's failure to ascertain the registration status of Select Health is further evidence of Respondent's failure to maintain effective controls against the diversion of listed chemicals.

As to factor two, Respondent's compliance with applicable law, the Government contends that Respondent failed to report to DEA transactions involving an ''extraordinary quantity'' of a listed chemical. Pursuant to 21 CFR 1210.05(a)(1) (1990 & 1991), a regulated person was required to report to DEA ''(a)ny regulated transaction involving an extraordinary quantity of a listed chemical.'' At the time of the 22 shipments to the California individual, Respondent was considered a regulated person and the shipments were considered regulated transactions. See 21 CFR 1310.01(e) and (f)(1) (1990 & 1991). The question then becomes whether these transactions involved an ''extraordinary quantity'' of a listed chemical requiring that they be reported to DEA.

''Extraordinary quantity'' is not defined. In a previous case, the Deputy Administrator evaluated the amount of listed chemical used for various purposes within the manufacturing industry and determined whether the amounts in question were ''extraordinary'' given the buyer the buyer's stated purpose. *See Alfred Khalily, Inc., d/b/a Alfa Chemical*, 64 FR 31289 (1999). However in this case, no such evaluation can be conducted. The Government did not present any evidence as to why the amount of ephedrine hydrochloride powder shipped to the individual by Respondent should be considered ''extraordinary.'' Therefore, the Deputy Administrator agrees with Judge Randall that the Government ''has failed to prove by a preponderance of the evidence that any of the transactions between the Respondent and (the individual) or Select Health involved an 'extraordinary quantity' of ephedrine or any other listed chemical.'' Thus there is no basis for the Deputy Administrator to conclude that Respondent violated 21 CFR 1310.05(a)(1).

The Government also asserts that pursuant to 21 U.S.C. 841(d)(3) it is unlawful for any person to knowingly or intentionally, ''with the intent of causing the evasion of the recordkeeping or reporting requirements of (the CSA) * * * (to) receive() or distribute() a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under (the CSA) is not required.'' From March 22, 1990 through January 2, 1991, Respondent made 22 shipments of ephedrine powder to the California individual and altered invoices to reflect sales of ephedrine tablets rather than ephedrine powder because no records were required for the shipment of ephedrine tablets in 1990 and 1991. Therefore, the Deputy Administrator concludes that Respondent failed to properly record and report these shipments of ephedrine powder and intentionally misrepresented the shipments on its invoices in violation of 21 U.S.C. 841(d)(3).

The Government further asserts that Respondent violated 21 U.S.C. 841(d)(2) which makes it unlawful for any person to knowingly or intentionally, ''possess() or distribute() a listed chemical knowing, or having reasonable cause to believe, that the listed chemical (would) be used to manufacture a controlled substance.'' In his plea agreement, Mr. Occhifinto stipulated that he knew that he had received funds from the individual originating from unlawful activity involving the manufacture and distribution of controlled substances. Therefore, the Deputy Administrator agrees with Judge Randall that ''Respondent, through Mr. Occhifinto, knew or had reason to believe that the ephedrine hydrochloride powder shipped to (California individual) would be used for diversionary purposes in violation of 21 U.S.C. 841(d)(2).''

The evidence also supports a conclusion that Respondent failed to ascertain whether Select Health was registered with DEA as required by 21 CFR 1310.07. Respondent was clearly aware of its responsibilities as evidenced by a letter it placed into evidence signed by its Senior Vice President to its customers indicating that Respondent needed a copy of its customers' registrations. However, there is no indication that Select Health received a copy of this letter. It is undisputed that Respondent shipped listed chemicals to Select Health from January 6 to October 28, 1998, without Select Health being registered with DEA or submitting a timely application for such registration.

The Government also contends that Respondent materially falsified its applications for registration in violation of 21 U.S.C. 843(a)(4)(A), by providing false information in explanation of its affirmative responses to the liability questions. Respondent however argues that it did not materially falsify its applications because it answered ''Yes'' to the liability questions; an explanation was offered; DEA was aware of Mr. Occhifinto's convictions at the time of the May 1997 applications; and neither Mr. Occhifinto nor Respondent had a motive to attempt to conceal Mr. Occhifinto's prior convictions.

The Deputy Administrator agrees with Judge Randall that the Government has failed to establish that Respondent materially falsified its applications since it did answer ''Yes'' to the liability questions. However, 21 U.S.C. 843(a)(4)(A) also makes it unlawful for any person to knowingly or intentionally ''omit any material information from any application * * *.'' Here, Respondent clearly failed to disclose on its applications Mr. Occhifinto's hashish convictions or his money laundering conviction. This omission is clearly material since Mr. Occhifinto is Respondent's president and from Respondent's explanation provided on the applications, DEA would not have been on notice of his convictions. The Deputy Administrator agrees with Judge Randall that ''(d)espite the Respondent's argument to the contrary, the absence of this information may be considered a material omission regardless of whether the DEA previously was aware of the convictions. * * * The registration application and the applicable law do not provide any exceptions for withholding information that already may be within the DEA's purview.'' Therefore, the Deputy Administrator concludes that Respondent omitted material information from its applications in violation of 21 U.S.C. 843(a)(4)(A).

The Deputy Administrator notes that there very well may have been a further material omission of information on the applications. Evidence introduced at the hearing by Respondent indicates that Mr. Occhifinto's traveling companion who gave him the bottles containing hashish was named Roland Bossi, and that Mr. Bossi was convicted of controlled substance related offenses. Further evidence introduced by Respondent indicates that the September 1997 letter sent to Respondent's customers regarding the need for a copy of customers' DEA registrations was signed by a Ron Bossi, Senior Vice President. The Deputy Administrator is concerned that this may be the same individual, however the Government presented no evidence to support such a conclusion. Therefore, the Deputy Administrator has not considered these suspicions in rendering his decision in this matter.

Pursuant to factor three, Mr. Occhifinto's convictions can be considered since he is Respondent's president. It is undisputed that in 1991,

Mr. Occhifinto was convicted of four counts relating to the smuggling of hashish. Mr. Occhifinto was sentenced to probation based upon his minimal participation. Further, Mr. Occhifinto, was also convicted in 1991 following his guilty plea to one count of money laundering as it related to his shipments of listed chemicals to the California individual. Mr. Occhifinto was ultimately sentenced in 1996 to 18 months incarceration followed by three years of supervised release.

As discussed under factor two, evidence in the record seems to suggest that Respondent's Senior Vice President, who appeared to have a much more significant role in the hashish smuggling endeavor was also convicted of controlled substance-related offenses. However, since no evidence was presented by the Government to indicate that it is the same individual, the Deputy Administrator has not relied on this information in rendering his decision.

Regarding factor four Respondent's experience in manufacturing and distributing listed chemicals, Respondent has manufactured and distributed pharmaceutical products since 1986. However, the record is clear that Respondent distributed listed chemicals from March 22, 1990 through January 2, 1991 knowing that they were to be used in the illicit manufacture of methamphetamine. In addition, as recently as 1998, Respondent was responsible for the distribution of approximately 3.5 million dosage units of a listed chemical to an unregistered customer.

As to factor five, Respondent's product was found at clandestine laboratories in 1990, which initiated the investigation of Respondent, and in 1998. While the evidence in the record does not support a finding that Respondent knew or had reason to believe that these chemicals were being diverted to the illicit manufacture of controlled substances, the Deputy Administrator agrees with Judge Randall that ''[d]espite what efforts the Respondent may be making to prevent such an occurrence, these products have been diverted.''

The Deputy Administrator agrees with Judge Randall that the Government has presented a prima facie case for denial of Respondent's applications for registration. However, there is evidence in the record regarding Mr. Occhifinto's extensive cooperation with law enforcement, his acceptance of responsibility for his actions, and his active involvement in religious and community-related charitable activities. Further, Mr. Occhifinto did not attempt to hide Respondent's dealings with Select Health and in fact reported to DEA that Select Health was not registered. But as Judge Randall noted, ''(w)hile the Respondent may be recognized for its efforts in reporting this violation to the DEA, refraining from any future transactions with Select Health, and in hiring a regulatory affairs representative, the fact remains that had greater preventative actions been taken, the thirty-six unlawful transactions never would have occurred. Remedial efforts are not superior to preventative actions.''

In her opinion, Judge Randall indicated that she is troubled by DEA's lack of action in this matter since the shipments to the California individual occurred in 1990 and 1991. Judge Randall stated that ''(b)y failing to act against the Respondent from 1991 until the Order to Show Cause in 1998, the Government has weakened its credibility in its argued concern for the public interest in light of the Respondent's past business activities. If the DEA believed then, what it now purports to argue, it should have acted at the time to limit or prohibit the Respondent's, or at least Mr. Occhifinto's, handling of listed chemicals.'' The Deputy Administrator disagrees with Judge Randall. There was no action that DEA could have taken, short of the criminal action that it did, or possibly civil action. Respondent did not even apply for registration until May 1997 and all applicants who submitted their applications by a specific date were allowed to continue in operation until action was taken regarding the applications

Judge Randall concluded, and the Deputy Administrator agrees, that despite Mr. Occhifinto's cooperation with law enforcement, his willingness to comply with DEA security requests, and his activities within the community, it is inconsistent with the public interest to issue Respondent a DEA registration. Respondent has failed to maintain effective controls against diversion as evidenced by its shipments to the California individual. Mr. Occhifinto has been convicted of two offenses related to the handling of controlled substances and listed chemicals. As recently as 1998, Respondent made a number of shipments of a listed chemical to an unregistered customer. Finally, no assurances have been made by Respondent that procedures are in place to prevent future transgressions. While Respondent has apparently hired a regulatory compliance officer, no evidence was presented concerning that individual's duties, responsibilities, and authority within Respondent. Also, no evidence was presented as to the extent of Mr. Occhifinto's participation in the daily operations of Respondent. As a result, the Deputy Administrator agrees with Judge Randall that one cannot ''adequately assess the weight to be given Mr. Occhifinto's prior egregious misconduct in determining the course of business to be followed in the future by the Respondent.'' Therefore, the Deputy Administrator concludes that Respondent's registration with DEA would be inconsistent with the public interest.

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 the applications for registration as an exporter of List I chemicals and as a manufacturer for distribution of List I chemicals, submitted by NVE Pharmaceuticals, Inc., be, and they hereby are, denied. This order is effective December 2, 1999.

Dated: October 25, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99–28603 Filed 11–1–99; 8:45 am]

BILLING CODE 4410–09–M

NATIONAL LABOR RELATIONS BOARD

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: National Labor Relations Board.

TIME AND DATE: 1 p.m., Friday, October 29, 1999.

PLACE: Board Conference Room, Eleventh Floor, 1099 Fourteenth St., NW, Washington DC 20570.

STATUS: Closed to public observation pursuant to 5 U.S.C. Section 552b(c)(2) (internal personnel rules and practices); Section 6 (information of a personal nature); (9)(B) (disclosure would significantly frustrate implementation of a proposed Agency action) and (c)(10) (deliberation on adjudicatory matters).

MATTERS TO BE CONSIDERED: Personnel Matters and Case Adjudication.

CONTACT PERSON FOR MORE INFORMATION: John J. Toner, Executive Secretary, National Labor Relations Board, 1099 14th Street NW, Suite 11600, Washington, DC 20570, Telephone: (202) 273–1940.

Dated, Washington, DC, October 26, 1999.