Company), Indianapolis, IN has been dropped as a Supporting Member.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and RITA intends to file additional written notification disclosing all changes in membership.

On September 28, 1995, RITA filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on April 3, 1996 (61 FR 14817).

The last notification was filed with the Department on September 27, 2002. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on November 6, 2002 (67 FR 67649).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 03–3293 Filed 2–10–03; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Sarnoff Corporation

Notice is hereby given that, on January 8, 2003, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Sarnoff Corporation has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are Sarnoff Corporation, Princeton, NJ; and E. I. du Pont de Nemours & Company, Wilmington, DE. The nature and objectives of the venture are to develop and demonstrate printable organic electronic materials and fabrication technologies for the production of thin film transistors on plastic substrates for use in low-cost displays.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 03–3297 Filed 2–10–03; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—VSI Alliance

Notice is hereby given that, on January 13, 2003, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), VSI Alliance has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Wael Badawy (individual member), Calgary, Alberta, CANADA; Barcelona Design, Inc., Newark, CA; Beijing Microelectronics Technology Institute, Fengtai, Beijing, PEOPLE'S REPUBLIC OF CHINA; CNRS–Centre Nationel De Recherche Scientifique, Paris, FRANCE; CPO Technologies Corporation, Sunnyvale, CA; Digeo Interactive LLC, Longmont, CO; Carolyn Hayden (individual member), Ottawa, Ontario, CANADA; Tomislav Ilic (individual member), San Francisco, CA; Jeda Technologies, Los Altos, CA; LSI Design & Integration Corporation (LDIC), San Jose, CA; NEC Electronics Corporation, Nakahara-ku Kawasaki, JAPAN; Vincent Ratford (individual member), San Jose, CA; WIS Technologies, San Jose, CA; and Christopher Wang (individual member), Costa Mesa, CA have been added as parties to this venture.

Also, Antrim Design Systems, Inc., Scotts Valley, CA; Co-Design Automation, Los Altos, CA; Dolphin Integration, Meylan, FRANCE; Embedded Solutions, Ltd., Abingdon, UNITED KINGDOM; Kyoto University-Department of Communications & Computer Engineering, Kyoto, JAPAN; Zainalabedin Navabi (individual member), Boston, MA; NEC Corporation, Nakahara-Ku Kawasaki, JAPAN; Nortel Networks, Nepean, Ontario, CANADA; Semifore Technologies, Irvine, CA; Simplex Solutions, Inc., Sunnyvale, CA; Spiratech Ltd., Radcliffe, UNITED KINGDOM; Spirea AB, Kista, SWEDEN; TransEDA, Eastleigh, UNITED KINGDOM; Prab Varma (individual member), Mountain View, CA; Vector 12 Corporation, Richmond, British Columbia, CANADA; and Verplex Systems, Inc., Milpitas, CA have been dropped as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and VSI Alliance intends to file additional written notification disclosing all changes in membership.

On November 29, 1996, VSI Alliance filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 4, 1997 (62 FR 9812).

The last notification was filed with the Department on October 9, 2002. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on November 8, 2002 (67 FR 68177).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 03–3296 Filed 2–10–03; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Penick Corporation, Inc., Grant Registration to Import Schedule II Substances

I. Background

On April 11, 2000, Penick Corporation, Inc. (Penick) applied to the Drug Enforcement Administration (DEA) for registration under 21 U.S.C. § 958(i) as an importer of coca leaves, raw opium, poppy straw, and poppy straw concentrate (narcotic raw materials or NRMs), all Schedule II controlled substances. On the same day, Penick also applied with DEA for registration as a manufacturer of a number of Schedule II controlled substances, including oxycodone, hydrcodone, morphine, hydromorphone and codeine. Pursuant to 21 CFR 1301.34(a), Mallinckrodt, Inc. (Mallinckrodt), and Normaco of Delaware, Inc. (Normaco), requested a hearing on Penick's application for registration as an importer of raw opium and concentrate of poppy straw (CPS). A hearing was held in Arlington, Virginia, on July 9 through 13 and August 13 through 15, 2001, with Penick, Noramco, Mallinckrodt and the Government participating and represented by counsel. All parties called witnesses to testify and introduced documentary evidence. After the hearing, all parties filed proposed findings of fact, conclusions of law, and argument. Penick, Moramco, and Mallinckrodt filed reply briefs.

On May 29, 2002, the Administrative Law Judge (ALJ) filed her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge. The ALJ recommended that Penick's Application be granted. Mallinckrodt and Noramco filed exceptions to the ALJ's recommended decision. Penick filed a response to the exceptions filed by Mallinckrodt and Noramco. After considering all of the evidence and post hearing submissions, the Deputy Administrator adopts the Filings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge in their entirety. They are incorporated into this final order as through they were set forth at length herein. The adoption of the ALJ's opinion 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.

II. Preliminary Matters

A. Regulatory Context

Because Penick is applying for both a renewal of its registration and permission to import, this proceeding is a combined adjudication and rulemaking. The rulemaking determines whether Penick may lawfully import into the United States the Schedule II controlled substances raw opium and CPS pursuant to 21 U.S.C. § 952(a). Penick has the burden of proof, and must establish by a preponderance of the evidence that such a rule can be issued. In order to do this, Penick must show by a preponderance of the evidence that the raw opium and CPS that it intends to import are ''necessary'' to provide for medical, scientific or other legitimate purposes.

The adjudication determines whether DEA should grant Penick's application for registration as an importer of the Schedule II controlled substances raw opium and CPS. In accordance with the DEA Statement of Policy and Interpretation on Registration of Importers, 40 FR 43,745 (1975), the Deputy Administrator will not grant Penick's application unless Penick establishes that the requirements of 21 U.S.C. § 958(a) and § 823(a) and 21 CFR 301.34(b)(1)–(7) are met to show that Penick's registration to import is in the public interest. DEA has the discretion to determine the weight assigned to each of the factors that must be considered to determine whether Penick's registration to import will granted. MD Pharmaceutical, Inc. v. DEA, No. 95–1267, 1996 U.S. App. LEXIS 1229 (D.C. Cir. 1996) (unpublished opinion.)

B. The Right to a Hearing

On December 19, 2000, Penick filed various motions requesting *inter alia,* that the objections to their registration be struck and that their application be summarily granted. As the basis for Penick's Motions, Penick asserted that because Organichem, Mallinckrodt, and Normaco are not bulk manufactures of the substances that Penick seeks to import, none of them had standing to object, comment upon, or request a hearing on Penick's application. Penick further asserted that none of the objecting manufactures had prudential standing to comment, object or request a hearing.

After a thorough review of the relevant parts of the Controlled Substances Act (CSA), the implementing regulations and the CSAS's legislative history, the ALJ found that the objecting manufacturers had standing to challenger DEA's action if it granted Penick's application. The ALJ also found that the CSA and its regulation do not expressly grant a right to hearing to importers of NRMs upon the application of another manufacture to import the same substance. She concluded, however, that DEA has the discretionary authority to afford that hearing right and that it has done so in other proceedings as well as the instant matter. On that basis, the ALJ denied the motion to strike. With respect to Penick's motion for an order, the ALJ determined that she has no jurisdiction over Penick's application to import coca leaves or poppy straw, which was not part of the hearing. Accordingly, the ALJ denied the Motion for an Order. The Deputy Administrator adopts the well-reasoned ruling of the ALJ in denying Penick's motions.

C. Designations of Confidentiality

Pursuant to a Protective Order issued by the Administrative Law Judge on April 26, 2001, and a Revised Protective Order issued on May 24, 2002, the parties filed various motions, both before and after the hearing, for the designation of certain testimony and exhibits as ''confidential'' and ''highly confidential.'' Some of the parties objected to the requests for confidentiality filed by other parties. After the hearing, the parties were provided an opportunity to file by motion requests for specifying such confidential material within the transcript. The Deputy Administrator has reviewed the pleadings on this issue, and hereby concurs with the Administrative Law Judge's orders on designations of confidentiality.

D. Motion To Reopen Record

On December 5, 2001, Normaco filed a letter asserting that Penick had changed its position with respect to the standard for registering applicants to import in a letter commenting on another manufacturers's application to import. Noramco moved to reopen the record in order for the ALJ to consider this letter. The ALJ concluded that no useful purpose would be served by considering Pencik's purported change of position, and denied Normaco's request. The Deputy Administrator concurs with the ALJ's decision denying the motion.

III. Final Order

The Deputy Administrator has carefully reviewed the entire record in this matter, as defined above, and hereby issues this final rule and final order prescribed by 21 CFR 1316.67 and 21 CFR 1301.46, based upon the following findings and conclusions.

A. The Rulemaking

As explained above, Penick cannot be registered as an importer of NRMs unless the Deputy Administrator finds that Penick will be allowed to import NRMs pursuant to 21 U.S.C. 952(a)(1). Because Penick is the proponent of such a rule, it must establish by a preponderance of the evidence that such a rule can be issued.

21 U.S.C. 952(a)(1) makes it unlawful to import controlled substances in Schedule I or II except ''such amounts of crude opium, poppy straw, concentrate of poppy straw and coca leaves as the Attorney General finds to be necessary to provide for medical scientific or other legitimate purposes.'' Whether Penick's importation of opium and CPS is ''necessary'' was not highly disputed at the hearing of this matter.

The ALJ found that it is undisputed that Penick seeks to import narcotic raw materials for legitimate uses. She also noted that the actual amounts of NRMs necessary for those uses is made in subsequent proceedings to establish quotas pursuant to 21 U.S.C. 826 and to grant permits to import pursuant to 21 CFR Part 1312, which are not part of this case. Accordingly, the Deputy Administrator adopts the ALJ's ruling and finds that Penick shall be permitted to import raw opium and CPS.

B. The Adjudication

Longstanding Federal policy prohibits the cultivation of the opium poppy in the United States, and also generally prohibits the importation of bulk narcotic alkaloids such as morphine and codeine. The NRMs raw opium and CPS therefore must be imported into the

United States for purposes of extracting morphine and codeine for pharmaceutical use. Following the extraction of these alkaloids, the manufacturers convert them into active pharmaceutical ingredients (APIs), such as oxycodone and hydrocodone. These APIs are then sold to other manufacturers to produce either dosage formulations or other APIs. The formulated drugs are then sold to drug wholesalers or directly to health care entities.

Noramco and Mallinckrodt are the only companies registered with DEA as importers of NRMs and bulk manufacturers of codeine and morphine. Penick has applied with DEA to be registered as an importer of NRMs, so that the company can manufacture its own codeine and morphine. Noramco and Mallinckrodt oppose Penick's application.

Any company that wishes to import NRMs must comply with the ''80–20 rule,'' which requires that 80 percent of the NRMs imported into the United States have their original source as Turkey and India. The remaining 20 percent must come from Yugoslavia, France, Poland, Hungary, or Australia. 21 CFR 1312.13(f).

Pursuant to 21 U.S.C. §§ 958a and 823(a), DEA is required to register Penick as an importer of Schedule I and II substances if the registration is ''consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' In determining the public interest, DEA must consider the factors enumerated at U.S.C. 823(a)(1)–(6) and 21 CFR 1301.34(b)(1)–(7), some of which are identical. Accordingly, the Deputy Administrator will first consider United States obligations under international treaties, then each of the factors delineated in 21 U.S.C. 823(a) and 21 CFR 1301.34(b)(1)–(7), as follows.[1]

1. Treaty Obligations

As the ALJ found, there is no evidence that the importation of NRMs by Penick would be inconsistent with United States obligations under international treaties, conventions or protocols. Under the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol (collectively, the Single Convention), the United States is obligated to take all necessary measures to ensure that the international movement of narcotics is limited to legitimate medical and scientific needs. Peter B. Bensinger, former Administrator of DEA, and Chuck Koczwara, Mallinckrodt's Director of Purchasing and Strategic Procurement, both testified that the primary goals of the Single Convention are to limit the manufacture, trade, and consumption of narcotic drugs to legitimate medical and scientific purposes; and ensuring availability of these drugs for medical use. Peter B. Bensinger also testified that any new registrant represents a potential for diversion, and that inasmuch as it is impossible to reduce the risk of diversion to zero, it is in the public interest to limit access to NRMs to a much smaller number of companies than would be appropriate in a free market.

The ALJ found, however, as explained below in consideration of the possibility of diversion of controlled substances, there is no evidence that entry of Penick into the market for importation of NRMs would result in significant diversion or contravene the Single Convention.

2. Maintenance of Effective Controls Against Diversion of Particular Controlled Substances and any Controlled Substance in Schedule I or II Compounded Therefrom Into Other Than Legitimate, Medical, Scientific, Research or Industrial Channels, by Limiting the Importation of and Bulk Manufacture of Such Controlled Substances to a Number of Establishments Which can Produce an Adequate and Uninterrupted Supply of These Substances Under Adequately Competitive Conditions for Legitimate Medical, Scientific Research, and Industrial Purposes

a. Diversion

The ALJ found that there is no evidence that specific activities involving Penick's importation of NRMs would increase diversion of those substances. John McRoberts, Penick's Vice President of Operations, testified extensively about Penick's internal security measures. The DEA Diversion Investigator (DI) who conducted the investigation of Penick's application testified favorably about Penick's security for shipments of NRMs from India and Turkey and Penick's distribution of its products via common carriers. The DI further testified that Penick's security systems and employee screenings met the requirements of DEA regulations. Neither Noramco nor Mallinckrodt adduced evidence that Penick's security arrangements were faulty.

Noramco Vice President Michael Kindergan testified that Penick's use of inefficient technology would increase the likelihood of diversion of opium in India because it would cause an increase in demand and in cultivation and production. Mr. Kindergan stated further that he believes that DEA personnel involved in investigating Penick's application focus on security within the manufacturing plant. Noramco does not claim that diversion from Penick's facility is likely; indeed, the manufacturing plant is probably the ''area of least exposure.'' However, because of the 80/20 rule, any new production of morphine will come from India, and in taking any action DEA should also consider that action's impact on the NRM market and on diversion at the grower level.

As the ALJ noted, however, there is nothing in the Single Convention treaty that would require a government agency to consider the impact on overseas diversion of NRMs. Accordingly, the ALJ found that DEA is not required to consider the impact on diversion in India in assessing Penick's application, a conclusion with which the Deputy Administrator agrees. Moreover, the Deputy Administrator found that even if the registration of Penick were to cause diversion of NRMs overseas, there is nothing in the Single Convention or DEA regulations that would require DEA to limit registration to import NRMs to only two companies, regardless of the adequacy of competition. Accordingly, the Deputy Administrator finds that this factor weighs in favor of Penick.

b. Adequate Competition

The issue of whether there is adequate competition in the NRM processing market was highly disputed. The ALJ conducted a thorough review of the evidence offered by the parties in coming to her conclusions. Under 21 CFR 1301.34(d), the Deputy Administrator is obligated to consider the following factors in determining whether competition is adequate.

(1) The extent of price rigidity in light of changes in raw materials and other costs and conditions of supply and demand.

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including (i) shifts in market shares and (ii) shifts in individual customers among domestic manufacturers.

(3) The existence of substantial differentials between domestic prices

[1] In this proceeding, Penick, as the applicant, has the burden of proof of showing that the public interest will be served by its registration to import NRMs. 21 CFR §§ 1301.44(c). Noramco and Mallinckrodt, however, have the burden of proving any propositions of fact or law asserted by them in the hearing. Id.; Roxane, 63 FR 55,891 (DEA 1998).

and the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufactures by the requirement of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event should an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his/her supply.

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

Michael I. Cragg, Ph.D. testified on behalf of Penick. Dr. Cragg concluded that Penick's reentry into the market will result in lower prices and a more reliable supply of narcotic products. Dr. Cragg relied upon theories of competition presented in economics literature to support the proposition that prices fall as the number of competitors increases. Dr. Cragg also testified that based upon the criteria used by the United States Department of Justice, competition in the narcotics industry is limited and Penick's reentry will increase competition. He found that at the critical stage of the production chain, competition is especially inadequate in the market for semi-processed APIs as there are only two importers and producers of semi-processed APIs, Johnson & Johnson and Mallinckrodt. Dr. Cragg explained that this situation creates a competitive bottleneck that affects all levels of the production chain. Despite this level of concentration, there has been no significant entry into the API market in the last decade. Furthermore, no entry has occurred despite the 150 percent increase in the size of the narcotics finished goods market from 1995 to 2000 and an almost five-fold increase in API revenues over that same period.

Dr. Cragg further testified that during this period of static duopoly, the prices of narcotic APIs have risen faster than when there were more competitors. From 1995 to 2000 estimated profits for narcotic APIs grew from $26 million to $246 million—a growth rate of 57 percent annually. Dr. Cragg concluded that these returns arose because revenues were growing faster than costs during the period when the number of importers was limited to only two. With respect to Penick's reentry into the NRM and API markets, Dr. Cragg expected such entry to raise the level of competition in the API market and lead to lower API prices.

Mark A. King, a consultant, testified on behalf of Noramco. He testified that Dr. Cragg's conclusions were incorrect, because they were based largely upon (1) a failure to consider structural factors inherent in the narcotic market as a whole; and (2) inaccurate data for NRM and API prices, and/or (3) selective application of general free market economic theories to one of the world's most highly regulated industries. Mr. King argued, in part, that NRM price increases have consistently outstripped the prices charged for narcotic APIs by Noramco during the period from 1995 to 2000; therefore, the value-added margins of narcotic APIs produced have declined, not increased. Mr. King also testified that Dr. Cragg's analysis was faulty because (1) he relied on Mallinckrodt's list prices in place of actual prices, (2) that U.S. API prices are driven not by industry concentration, but by DEA's policy of prohibiting the domestic cultivation and processing of opium poppies and (3) there is no persuasive evidence that Noramco or Mallinckrodt have been able to exert inordinate power over purchasers of APIs.

Walter H.A. Vandaele, Ph.D. testified on behalf of Mallinckrodt. Dr. Vandaele concluded generally that there is considerable competition between Mallinckrodt and Noramco in the bulk narcotic API market. Dr. Vandaele argued that significant discounting of list price and frequent switching by large customers from one bulk supplier to another evidence a significant degree of competition in the current market. Significant increases in bulk API prices reflect higher marginal costs of supplying increased demand in the face of tight supplies of raw material. Bulk suppliers' partial downstream integration into finished products provides no increase in their ability to price anti-competitively. Dr. Vandaele further argued that Penick's entry as an NRM importer and bulk API supplier would provide an insignificant impact on the level of competition in either the bulk API market or the narcotic finished product market, and no measurable impact on consumer prices.

The Deputy Administrator agrees with the ALJ that Penick has demonstrated that the opiate API market was not operating under ''adequately competitive conditions'' as of the date of the hearing. As the ALJ noted, it is undisputed that prices of APIs increased substantially during the 1990s. With respect to the other factors listed in 21 CFR 1301.34(d), The Deputy Administrator also agrees with the ALJ that the customer switches referenced in the records do not demonstrate strong competition. With respect to the other factors listed, the Deputy Administrator agrees with the ALJ that they are not relevant in this case or the record is not sufficient to warrant a finding. Having found that the market is not adequately competitive, the Deputy Administrator concludes that this factor weights in favor of granting Penick's application, even though Noramco and Mallinckrodt are capable of maintaining an adequate and uninterrupted supply.

3. Compliance with Applicable State and Local Law;

Penick adduced evidence that it was substantially in compliance with state and local law, and Noramco and Mallinckrodt did not produce evidence to the contrary. The Deputy Administrator therefore finds that this factor weighs in favor of granting Penick's application.

4. Promotion of Technical Advances in the Art of Manufacturing these Substances and the Development of new Substances.

The evidence showed that Penick has patented processes to produce oxycodone and narcotic antagonists from morphine or codeine instead of thebaine, and has invented processes to produce hydrocodone and hydromorphone. There was also evidence that Penick has a more efficient process to produce oxycodone from thebaine in that Penick is able to utilize both opium and CPS as the raw materials for producing various opiate APIs. There was further evidence that Penick plans to upgrade its facilities and has committed at least $30 million to the projects.

Noramco adduced evidence, on the other hand, that Penick's proposed technology for producing oxycodone is not as efficient as Noramco's technology, and both Noramco and Mallinckrodt emphasized that Penick's proposed processes have not been tested in commercial production. Noramco also claimed that Penick had not demonstrated the necessary commitment of resources to adequately upgrade its operation.

While there is controversy over the quality of Penick's proposed technology that cannot be resolved by the record in this matter, The Deputy Administrator concludes that Penick's patents and

development of manufacturing processes promote technical advances in the manufacture of controlled substances. Therefore this factor weighs in favor of granting Penick's application.

5. Prior Conviction Record of Applicant under Federal and State Laws Relating to the Manufacture, Distribution, or Dispensing of such Substances;

It is undisputed that neither Penick nor any of its officer, agents, or key employees has been convicted of any Federal or State law relating to the manufacture, distribution, or dispensing of controlled substances. The Deputy Administrator therefore concludes that this factor weighs in favor of granting Penick's application.

6. Past Experience in the Manufacture of Controlled Substances and the Existence in the Establishment of Effective Controls Against Diversion.

The evidence showed that Penick manufactured narcotics from 1947 until sometime in the 1990s. Although Mallinckrodt and Noramco asserted that regulatory requirements have changed since Penick exited the market, they adduced no evidence that Penick would be unable to comply with current or future requirements.

Penick presented evidence of its security systems and procedures, and Noramco and Mallinckrodt acknowledge that there is little likelihood of diversion from Penick's plant. The Deputy Administrator therefore concludes that this factor weighs in favor of granting Penick's application.

7. Such other Factors as may be Relevant to and Consistent with the Public Health and Safety.

The ALJ found three factors relevant to the public health and safety:

a. *Diversion of Opium:* Both Noramco and Mallinckrodt asserted that Penick's importation of NRMs would be likely to result in increased diversion of opium in India. The ALJ found that DEA is not required to consider the impact on diversion in India in assessing Penick's application. She also found that such claims were speculative at best. The Deputy Administrator agrees that this consideration need not be addressed under this factor. The Deputy Administrator also finds, however, that nothing in the Single Treaty or DEA regulations requires DEA to attempt to eliminate diversion by limiting the licensing of NRM importers to two companies, despite the absence of competition.

b. *Waste of Narcotic Raw Materials:* Noramco and Mallinckrodt also asserted that Penick's unproven technology will result in the waste of scarce NRMs. The ALJ found these assertions speculative because Penick could not begin its scaling up of operations until it obtained a registration to manufacture Schedule II controlled substances. The Deputy Administrator agrees with the ALJ that these contentions are too speculative to warrant consideration.

c. *Compliance with Federal Statutes and Regulations:* Although DEA found Penick to have committed numerous record keeping violations in a 1988 investigation, with Penick paying $40,000 to settle a consequent civil action, the DI testified that subsequent DEA regulatory investigations indicated that Penick was substantially in compliance with DEA requirements. With respect to FDA regulations, Penick has not been cited for any deficiencies since a 1993 warning letter. With respect to EPA requirements, the evidence showed that Penick hold the requisite permits and is operating within them and that any remediation issues with the New Jersey Department of Environmental Protection are the responsibility of Bestfoods rather than of Penick.

C. Exceptions

Both Noramco and Mallinckrodt filed exceptions to the Administrative Law Judge's Recommended Ruling, Findings of Fact, Conclusions of Law and Decision. Penick responded to those exceptions. Having considered the record in its entirety, including the parties' exceptions and responses, the Deputy Administrator finds no merit in Noramco and Mallinckrodt's exceptions, all of which concerned matters that were addressed at length at the hearing. The exceptions were extensive and are part of the record. Only some of the exceptions merit further discussion, and they will not be restated at length herein.

In its exceptions, Noramco contends that the ALJ failed to give consideration to the risk of diversion both inside and outside the United States, (2) securing an adequate supply to meet the needs of the medical community and (3) ensuring that the prices consumers pay for pain medication and narcotic APIs are reasonable and not inflated.

With regard to diversion within the United States, Noramco urges consideration of Penick's compliance history. At the hearing, however, the ALJ considered Penick's compliance history and did not find it evidence of the possibility of increased diversion. The DI testified that although a 1988 DEA investigation revealed numerous record keeping violations, requiring Penick to pay $40,000 to settle a civil action, inspections since 1994 have shown Penick to be substantially in compliance with record keeping requirements. In May 1990 the FDA found three deficiencies. Penick promised to correct two of them and to make some corrections to the third. Pursuant to an anonymous compliant that Penick was making narcotics and antibiotics in an unsanitary manner, FDA investigators conducted another inspection in June 1991; the inspectors found no problems. The FDA inspected Penick again in January and February 1993 and raised a number of concerns. A warning letter was issued to Penick in March 1993 alleging various deficiencies in Penick's validation processes and record keeping and a lack of sufficient quality control personnel. Following correspondence between the FDA and Penick, the FDA inspected again in September 1993 and found that Penick has corrected the deficiencies. Penick underwent another FDA inspection in August 1996 and no deficiencies were found. Thus, while Penick has regulatory problems in 1988, it has been substantially in compliance with DEA regulations since 1994. The 1988 violations, and the apparently minor problems with FDA regulatory compliance on a few occasions in the 90s, do not rise to a level that would warrant a denial of Penick's registration based on the possibility of increased diversion.

Noramco also argues that registration of *any* new participants increases the risk of diversion, and that the ALJ correctly determined that Noramco and Mallinckrodt have the means and capacity to produce an adequate and uninterrupted supply of APIs. As these issues were adequately discussed in the ALJ's recommended decision, there is not need for further discussion here.

Noramco also contends that competition is adequate in the active pharmaceutical ingredient market, citing the ALJ's statement that she did expect Penick's entry into the market to have a significant impact on the prices that consumers pay for opiate drugs. Noramco fails to note, however, that despite conclusion, the ALJ also concluded that Penick has demonstrated that the opiate active pharmaceutical ingredient market was not operating under ''adequately competitive conditions.''

Mallinckrodt also filed exceptions to the ALJ's opinion and recommended ruling. In its first exception, Mallinckrodt argues that the ALJ erred in finding that competition was inadequate. The Deputy Administrator finds, however, that all of

Mallinckrodt's arguments in this regard were thoroughly considered by the ALJ at the hearing and in her opinion and recommended ruling. Accordingly, the exception does not warrant consideration.

Mallinckrodt further argues that it is not in the public interest to register Penick when supply is adequate. Mallinckrodt contends that the ALJ failed to take into account the large investments of Noramco and Mallinckrodt, versus the lesser amount of investment by Penick. Mallinckrodt fails to provide a reasonable explanation, however, of how the size of the parties' investments would effect the adequacy of supply.

Mallinckrodt also contends that Penick's technology does not support its registration. It asserts that there is no evidence that Penick has an efficient technology for producing hydrocodone and that Penick's method of making oxycodone is outdated. As the ALJ noted, however, there is clearly some controversy over the quality of Penick's proposed technology, a controversy that the ALJ concluded the record was not sufficient to resolve. The ALJ concluded, however, that Penick's patents and development of processes promote technical advances in the manufacture of controlled substances. Under 21 U.S.C. 823(a)(3), that factor, along with the development of new substances, is all that is to be considered. Accordingly, the Deputy Administrator agrees with the ALJ and concludes that this factor weighs in favor of granting Penick's registration.

Mallinckrodt argues further that the ALJ erred in not considering the impact on diversion in the overseas NRM market. Mallinckrodt contends that in later cases, DEA has taken the position that such issues are relevant. This issue has been fully discussed in the ALJ's recommended decision and hereinabove. Moreover, the Deputy Administrator finds that even if the possibility of increased diversion overseas were taken into account, Noramco and Mallinckrodt's arguments in this regard are too speculative to warrant serious consideration.

Finally, Mallinckrodt argues that at a minimum, the ALJ should have recommended that conditions be placed on Penick's registration. Having reviewed the record in it's entity, the Deputy Administrator concludes that the evidence showed that Penick does not intend to use its registration as a ''shelf registration.'' There is sufficient evidence, and no controverting evidence, that Penick had made concrete plans to upgrade and expand its controlled substance manufacturing facilities once it is clear that Penick will receive requisite DEA registrations.

IV. Conclusion

Based upon the foregoing, the Deputy Administrator finds that it is in the public interest, as defined by 21 U.S.C. 823(a)(1)–(6) and 21 CFR 1301.34(b)(1)–(7), to grant Penick's application to be registered as an importer of NRMs. In light of Penick's long experience in manufacturing bulk pharmaceuticals, including opiates, it is not necessary to grant a conditional application. This decision is effective March 13, 2003.

Dated: January 29, 2003.

John B. Brown, III,

Deputy Administrator.

[FR Doc. 03–3299 Filed 2–10–03; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP(OVAW)–1373]

Meeting of the National Advisory Committee on Violence Against Women

AGENCY: Office on Violence Against Women, Office of Justice Programs, Justice.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming public meeting of the National Advisory Committee on Violence Against Women (hereinafter ''the Committee'').

DATES: The meeting will take place on February 20 from 9 a.m.–5 p.m., and on February 21 from 9 a.m.–2:15 p.m.

ADDRESS: The meeting will take place at the Adolphus Hotel, 1321 Commerce Street, Dallas, Texas 75202.

FOR FURTHER INFORMATION CONTACT: Omar A. Vargas, Special Assistant, The National Advisory Committee on Violence Against Women, 810 Seventh Street, NW, Washington, DC 20531. Telephone: (202) 307–6026. E-mail: *AskNAC@ojp.usdoj.gov* Fax: (202) 307–3911. View the Committee's Web site at: *http://www.ojp.usdoj.gov/vawo/nac/welcome.html*

SUPPLEMENTARY INFORMATION: The Committee is chartered by the Attorney General, and co-chaired by the Attorney General and the Secretary of Health and Human Services (the Secretary), to provide the Attorney General and the Secretary with practical and general policy advice concerning implementation of the Violence Against Women Act of 1994, the Violence Against Women Act of 2000, and related laws, and will assist in the efforts of the Department of Justice and the Department of Health and Human Services to combat violence against women, especially domestic violence, sexual assault, and stalking.

In addition, because violence is increasingly recognized as a public health problem of staggering human cost, the Committee will bring national attention to the problem of violence against women and increase public awareness of the need for prevention and enhanced victim services.

This meeting will primarily focus on organizational and planning aspects of the Committee's work; however there will be an opportunity for public comment on the Committee's role in providing general policy guidance on implementation of the Violence Against Women Act of 1994, the Violence Against Women Act of 2000, and related legislation.

Meeting Format

This meeting will be held according to the following schedule:

1. *Date:* Thursday, February 20, 2003.
Time: 9 a.m.–5 p.m., including breaks.
2. *Date:* Friday, February 21, 2003.
Time: 9 a.m.–11:45 am, sub-committees will convene in sessions not open to the public. 12 p.m.–2:15 p.m., the whole Committee will reconvene in a session open to the public.

The meeting scheduled for February 20, 2003 will begin with presentations from invited speakers representing Violence Against Women Act implementation by the Departments of Justice, and Health and Human Services. After the presentations by invited speakers, Committee members will consider their charge and convene subcommittees. Time will be reserved for comments from the public, beginning at 4:30 p.m. and ending at 5 p.m. See the section below on Reserving Time for Public Comment for information on how to reserve time on the agenda.

The meeting scheduled for February 21, 2003, will consist of review and discussion by the Committee of the charge and reports by the subcommittees regarding the Committee's work-plan and forthcoming recommendations to the Attorney General and the Secretary.

Attending the Meeting

The meeting on February 20, and the afternoon session of the meeting on February 21, will be open to the public. (The Committee will convene in closed sub-committee sessions on the morning of February 21, 2003, pursuant to 41