

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 complaint 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