

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 Koczvara, 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 Kinderger 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. Kinderger 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).