

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 be 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 LEXIS 1229 (D.C. Cir. 1996) (unpublished opinion.)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 challenge 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. Normaco 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 Penick'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 use. 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