DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 01–3]

Penick Corp., Newark, New Jersey; Notice of Administrative Hearing, Summary of Comments and Objections; Notice of Hearing

This Notice of Administrative Hearing, Summary of Comments and Objections, regarding the application of Penick Corporation (Penick) for registration as an importer of the Schedule II controlled substances coca leaves, raw opium, poppy straw, and poppy straw concentrate is published pursuant to 21 CFR 1301.34(a). On August 18, 200, notice was published in the **Federal Register**, 65 FR 50568 (DEA 2000), stating that Penick has applied to be registered as an importer of coca leaves, raw opium, poppy straw, and poppy straw concentrate.

Both Noramco of Delaware, Inc. (Noramco), and Mallinckrodt, Inc. (Mallinckrodt), timely filed comments and objections to and requested a hearing on Penick's application. Organichem Corporation (Organichem) filed comments on Penick's application. Notice is hereby given that a hearing with respect to Penick's application to be registered as an importer of raw opium and of poppy straw concentrate will be conducted pursuant to the provisions of 21 U.S.C. 952(a) and 958 and 21 CFR 1301.34.

Hearing Date

The hearing will begin at 9:30 a.m. on July 9, 2001, and will be held at the Drug Enforcement Administration Headquarters, 600 Army Navy Drive, Hearing Room, Room E–2103, Arlington, Virginia. The hearing will be closed to any person not involved in the preparation or presentation of the case.

Notice of Appearance

Any person entitled to participate in this hearing pursuant to 21 CFR 1301.34, and desiring to do so, may participate by filing a notice of intention to participate, in triplicate, and in accordance with 21 CFR 1301.34, with the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, DC 20537, within 30 days of the date of publication of this notice in the **Federal Register**. Each notice of appearance must be in the form prescribed in 21 CFR 1316.48. Penick, Noramco, Mallinckrodt, and DEA Office of Chief Counsel need not file a notice of intention to participate.

FOR FURTHER INFORMATION CONTACT: Helen Farmer, Hearing Clerk, Drug Enforcement Administration, Office of Administrative Law Judges, Washington, DC 20537; Telephone (202) 307–8188.

Summary of Comments and Objections

Mallinckrodt's Comments

Mallinckrodt states that Penick has not manufactured controlled substances for the last ten years and is now owned by a company with no experience in controlled substance manufacturing or importation, that consequently Penick would likely be wasteful in manufacturing opiate based products, and that the ability of current registrants to provide and maintain an adequate and uninterrupted supply of controlled substances would be undermined. Mallinckrodt contends that it, unlike Penick, has taken significant efforts to maintain adequate and uninterrupted supplies of active pharmaceutical ingredients.

Mallinckrodt further asserts that the United States is obligated to limit the international shipment of narcotics to the minimum to meet medical and scientific needs, and that inasmuch as the current registrants can adequately supply those needs, it is inconsistent with the United States' treaty obligations under the Single Convention on Narcotic Drugs to register Penick to import raw opium and poppy straw concentrate.

Mallinckrodt also states that Penick has a history of ''marginal compliance'' with DEA regulations, and that if it resumes manufacturing controlled substances it will be unable to comply with Environmental Protection Agency and Food and Drug Administration requirements. Mallinckrodt contends that competition among domestic manufacturers is adequate, that registering Penick will not enhance competition, and that any difference between domestic and foreign prices of relevant substances reflects the regulations and policies faced by domestic producers. Finally, Mallinckrodt states that Penick's lack of adequate manufacturing facilities indicates that it is not capable of maintaining effective controls against diversion.

Noramco's Comments

Noramco asserts that because Penick has not produced significant quantities of bulk narcotic substances since 1991, it will be difficult for Penick to produce these materials as efficiently as existing registrants, thereby aggravating the long-term shortage of narcotics raw materials. Noramco also states that existing manufacturers of bulk narcotic substances are producing an adequate and uninterrupted supply under adequately competitive conditions, that Penick's troubled financial history raises concerns regarding its ability to manufacture narcotic substances in a manner consistent with the public interest, and that Penick will have to demonstrate that it can effectively control diversion. Additionally, Noramco asserts that Penick's management intends to fund the business with a sum that is inadequate to the task of starting and maintaining a viable narcotic raw material import and bulk manufacturing business.

Organichem's Comments

Organichem states that Penick's financial difficulties have prevented it from heretofore operating successfully, that it should be required to comply with current DEA security requirements, and that it should also be required to demonstrate that it can meet current Food and Drug Administration, environmental, and international standards.

Organichem further asserts that Penick should be required to demonstrate that it has the financial resources necessary to finance production and a business plan adequate to establish and maintain a profitable business.

Dated: May 29, 2001.

Donnie R. Marshall,

Administrator, Drug Enforcement Administration.

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DEPARTMENT OF LABOR

Employment and Training Administration

ETA–9016 Report on Alien Claimant Activity; Comment Request

ACTION: Notice; request for comments

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with a provision of the Paperwork Reduction Act of 1995 at 44 U.S.C. 3506(c)(2)(A). This program helps to ensure that requested data can be provided in the desired format, reporting burdens (time