

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, 2000, 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

and financial resources) are minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed revision/extension for collection of the ETA-9016 Report on Alien Claimant Activity. A copy of the proposed information collection request can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before August 6, 2001.

ADDRESSES: Office of Workforce Security, Employment and Training Administration, U.S. Department of Labor, Attn: Bob Whiting, Room S-4522, 200 Constitution Avenue NW, Washington, DC 20210. Telephone number: (202) 693-3215 (this is not a toll-free number). Fax: (202) 693-3229. E-mail: rwhiting@doleta.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The ETA-9016 Report is used by the Department of Labor to assess whether (and the extent to which) the requirements of the Immigration and Naturalization Service (INS), Systematic Alien Verification for Entitlement (SAVE) system are cost-effective and otherwise appropriate for the Unemployment Insurance (UI) program. In addition, data from the Alien Claims Activity report is being used to assist the Secretary of Labor in determining whether a State Employment Security Agency's administrative costs associated with the verification program are reasonable and reimbursable. There is no other report or system available for collecting this required information. The report allows the Department of Labor to determine the number of aliens filing for UI, the number of benefit issues detected, the denials of benefits to aliens, the extent to which State Agencies use the system, and the overall effectiveness and cost efficiency of the verification system. If SESAs are not required to submit the information on the Alien Claims Activity Report, the Department of Labor would not be able to fulfill its responsibilities to assess the SAVE system.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

In the year 2000, over 1.172 million UI claimants were identified by the SESAs as aliens, constituting almost eight percent of UI claims taken in the nation. Continued collection of the ETA-9016 data will provide for a comprehensive evaluation of alien claims activity. The data is collected quarterly, and an analysis of the data is made for each one-year period. The most recent analysis identified concerns with the consistency of the interpretation of the reporting instructions among the SESAs, each of whom must apply the instructions to claimstake procedures that vary significantly. In order to encourage more consistency in the reporting by the SESAs, changes are being proposed that will simplify the reporting and decrease the burden.

Currently, seven items are reported on the ETA-9016 Report:

1. Initial claims where claimant is not a citizen.
2. Number of claimants verified through the INS designated automated system.
3. Number of secondary (mail) verifications through the INS.
4. Nonmonetary determinations resulting from the verification in items number 2 and/or 3.
5. Denials resulting from issues in item number 4.
6. Nonmonetary determinations on the alien issue not a result of verification through the INS designated automated system or secondary INS verification.
7. Denials resulting from issues in item number 6. ETA proposes to consolidate items 4-7 into two items as follows:

- Nonmonetary determinations on the alien issue.

- Denials resulting from the nonmonetary determinations on the alien issue.

The effectiveness of the SAVE verification process is well established. For the year 2000, it is estimated that over \$24 million was realized by identifying and denying benefits to ineligible aliens through the SAVE process. The total savings for the past 10 years is estimated at over \$100 million. Thus, it is no longer deemed necessary to justify use of the SAVE process on a national basis.

Consolidation of the reporting items on nonmonetary determinations will eliminate the distinction between issues detected through the SAVE process and issues detected through other means, as will consolidation of the reporting items on denials. The Department of Labor believes that this will simplify the reporting process by reducing the burden, with no corresponding loss of the Department of Labor's ability to evaluate the effectiveness and cost efficiency of the SAVE process in the individual SESAs.

Type of Review: Revision.

Agency: Employment and Training Administration.

Title: Alien Claims Activity Report.

OMB Number: 1205-0268.

Agency Number: ETA-9016.

Affected Public: State Governments.

Total Respondents: 53 State Agencies.

Frequency: Quarterly.

Total Responses: 212.

Average Time per Response: 1 hour.

Estimated Total Burden Hours: 212 hours.

Total Burden Cost (capital/startup): \$10,200 which is a one time cost of reprogramming the State systems.

Total Burden Cost (operating/maintaining): \$5300 which is allowable cost under the administrative grants awarded to States by the Federal government.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 29, 2001.

Cheryl Atkinson,

Director, Office of Income Support.

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