

Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with section 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on January 26, 1999, Roxane Laboratories, Inc., 1809 Wilson Road, P.O. Box 16532, Columbus, Ohio 43216-6532, made application by renewal to the Drug Enforcement Administration to be registered as an importer of cocaine (9041), a basic class of controlled substance listed in Schedule II.

The firm plans to import cocaine to make products for distribution to the firm's customers.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than (30 days from publication)

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 CFR 1301.34(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: March 3, 1999.

**John H. King,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Importation of Controlled Substances; Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with section 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on November 30, 1998, Taro Pharmaceuticals U.S.A., Inc., 5 Skyline Drive, Hawthorne, New York 10532, made application to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed below:

Drug	Schedule
Pentobarbital (2270) .....	II
Codeine (9050) .....	II
Oxycodone (9143) .....	II
Hydrocodone (9193) .....	II

The firm plans to import finished product sample for evaluation and conducting clinical/Bio-equivalence testing.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of these basic classes of controlled substances may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C.

20537, Attention: DEA Federal Register Representative (CCF), and must be filed no later than May 3, 1999.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: January 27, 1999.

**John H. King,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 98-25]

#### George Thomas, PA-C Denial of Application

On March 19, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to George Thomas, PA-C (Respondent) of Richland, Washington. The Order to Show Cause notified him of an opportunity to show cause as to why DEA should not deny his application for registration as a mid-level practitioner pursuant to 21 U.S.C. 823(f) and 824(a)(3), for reason that his registration would be inconsistent with the public interest and that he is not currently authorized to handle controlled substances in the State of Washington.

By letter dated April 13, 1998, Respondent filed a request for a hearing and the matter was docketed before Administrative Law Judge Gail A. Randall. On April 20, 1998, Judge Randall issued an Order for Prehearing Statements. In lieu of filing a prehearing statement, the Government filed a Motion for Summary Disposition on May 5, 1998, alleging that Respondent was not authorized to handle controlled substances in the State of Washington and therefore DEA cannot issue him a registration in that state. Respondent

did not reply to the Government's motion.

On May 27, 1998, Judge Randall issued an Order denying the Government's motion. In doing so, Judge Randall agreed with the Government that DEA lacks authority to register a practitioner who is not authorized to handle controlled substances in the state in which he practices. However, Judge Randall found that the Government had not met its burden of proof for summary disposition since the Government failed to file a copy of Respondent's application or any other evidence indicating that Respondent had applied to be registered by DEA in the State of Washington. Thereafter, on June 9, 1998, the Government filed a Motion for Reconsideration of Summary Disposition Motion, arguing that it had met its burden of proof, but nonetheless attaching a copy of Respondent's application which reflected an address in Richland, Washington.

Respondent filed a response to the Government's motion on June 26, 1998. In his response, Respondent made three requests: (1) to withdraw the DEA application dated January 16, 1997; (2) that future applications be processed in an expedient and timely manner; and (3) that a future application will be handled favorably, as long as the Respondent holds the appropriate state license. On July 13, 1998, the Government contended that pursuant to 21 CFR 1301.16(a) and 28 CFR 0.100 and 0.104, Judge Randall lacked jurisdiction to grant Respondent's request to withdraw his pending application. In a footnote, the Government indicated that Respondent's request to withdraw his application had been forwarded to the DEA Deputy Assistant Administrator, Office of Diversion Control.

On July 23, 1998, Judge Randall issued her Opinion and Recommended Ruling, concluding that she lacked jurisdiction to grant Respondent's request to withdraw his application; finding that Respondent lacked authorization to handle controlled substances in the State of Washington; granting the Government's Motion for Summary Disposition; and recommending that Respondent's application for registration be denied. Neither party filed exceptions to her opinion, and on September 1, 1998, Judge Randall transmitted the record of these proceedings to the Acting Deputy Administrator.

In a letter dated January 5, 1999 to DEA's Chief Counsel, the Deputy Administrator sought clarification regarding the status of Respondents

application in light of Government counsel's representation that Respondent's request to withdraw his application had been forwarded to the DEA Deputy Assistant Administrator, Office of Diversion Control for a decision. The Deputy Administrator reasoned that if Respondent's request to withdraw his application had been granted then there is no application to deny and these proceedings are moot. By letter dated February 22, 1999, DEA's Chief Counsel indicated that Respondent's request to withdraw his application was denied and attached a copy of the August 12, 1998 letter from DEA's Deputy Assistant Administrator, Office of Diversion Control denying Respondent's request.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator, adopts in full, the Opinion and Recommended Ruling of the Administrative Law Judge.

The Deputy Administrator finds that effective on or about October 5, 1997, Respondent entered into an Agreed Order with the State of Washington, Department of Health, Medical Quality Assurance Commission. As part of the Agreed Order, Respondent agreed that he shall not order, prescribe or dispense controlled substances. Based upon the evidence in the record this Agreed Order is still in effect and Respondent does not dispute that he is without authority to handle controlled substances in the State of Washington.

The DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts his business. 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See *Romeo J. Perez, M.D.*, 62 FR 16193 (1997); *Demetris A. Green M.D.*, 61 FR 60728 (1996); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993).

Here it is clear that Respondent is not authorized to handle controlled substances in Washington. Therefore, he is not entitled to a DEA registration in that state.

The Deputy Administrator further finds that in light of the above, Judge Randall properly granted the Government's Motion for Summary Disposition. It is well settled that when no question of material fact is involved, or when the facts are agreed upon, there is no need for a plenary, administrative hearing. Congress did not intend for

administrative agencies to perform meaningless tasks. See *Gilbert Ross, M.D.*, 61 FR 8664 (1996); *Philip E. Kirk, M.D.*, 48 FR 32887 (1983), *aff'd sub nom Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984). Here, there is no dispute that Respondent currently lacks state authority to handle controlled substances in Washington, where he has requested to be registered with DEA.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for a DEA Certificate of Registration submitted by George Thomas, PA-C, be, and it hereby is, denied. This order is effective May 3, 1999.

Dated: March 15, 1999.

**Donnie R. Marshall,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**ACTION:** Notice of Information Collection under Review: Application for Certificate of Citizenship in Behalf of an Adopted Child.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on January 14, 1999 at 64 FR 2517, allowing for a 60-day public comment period. No comments were received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until May 3, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer,