

Centre of New Jersey, 661 Highway One, North Brunswick, New Jersey 08902, made application by renewal to the drug Enforcement Administration to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import the listed controlled substances to manufacture amphetamine.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class 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, DC 20537, Attention: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed no later than September 13, 2003.

This procedure is to be conducted simultaneously with an 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 1311.42(a), (b), (c), (d), (e) and (f) are satisfied.

Dated: June 25, 2003.

Laura M. Nagel,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Deanwood Pharmacy: Denial of Application for Registration

I. Background

On September 5, 2001, the Deputy Assistant Administrator, Office of

Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Deanwood Pharmacy (Respondent) of Washington, DC, notifying Respondent of an opportunity to show cause as to why DEA should not deny its application for DEA registration as a pharmacy pursuant to 21 U.S.C. 824(a)(2) and (3) and 823(f), on the ground that such registration would be inconsistent with the public interest. As a basis for revocation, the Order to Show Cause alleged that (1) Respondent's employee, Mr. Watson, was hired in violation of 21 CFR 1301.76, since the Respondent did not seek a waiver of this provision prior to hiring him; (2) that Mr. Watson had used Deanwood Pharmacy's previous DEA Certificate of Registration to purchase various controlled substances for his personal use; (3) that in April 1999, DEA investigators performed an accountability audit of controlled substances, resulting in a finding of overages and shortages of the audited drugs; and (4) that on October 22, 1999, Mr. Watson was convicted, upon entry of a guilty pleas, of an offense related to this handling of controlled substances.

By letter filed on October 12, 2001, the Respondent's owner requested a hearing in this matter. On November 6, 2001, Administrative Law Judge Gail A. Randall (the ALJ) issued an Order for Prehearing Statements. On November 15, 2001, the Government filed a Motion for Summary Disposition (Motion).

The Government attached to its Motion an affidavit from Antoinette J. Williams, the Chief of DEA's registration had been surrendered on April 2, 1999, and that the Respondent had submitted a new application for a DEA Certificate of Registration for a retail pharmacy on or around April 12, 1999. The Government also attached a letter dated August 1, 2001, from the Government of the District of Columbia, Department of Health, asserting that Deanwood Pharmacy did not have a current pharmacy license or DC Controlled Substance Registration.

Based on the attachments, the Government argued that the Respondent did not have a valid license to operate a pharmacy or to handle controlled substances in the jurisdiction of his requested DEA certificate. Accordingly, the Government asserted that the Respondent's pending DEA application must be denied.

After numerous extensions of time and motions to stay proceedings, the ALJ issued an Order on January 30, 2002, giving the respondent until February 22, 2002, to respond to the Government's Motion. On that date, the Respondent filed an Opposition to

Government's Motion for Summary Disposition, asserting that the Respondent had a pending application filed on January 11, 2002, before the Department of Health for the District of Columbia, (Department of Health) for a controlled substances registration. The Respondent also noted that the Government contacted the Department of Health on or about January 18, 2002, and provided that office the information in the show cause order in this matter. As a result of the exchange of information, the Respondent now believed that the Department of Health's decision regarding the application for authority to handle controlled substances would not be resolved for several months. Accordingly, the Respondent asked that this matter be stayed until a decision was rendered by the Department of Health, in order to avoid further delay in DEA's processing of Respondent's application. The Respondent did not disagree with the Government's assertions that the Respondent was currently not authorized to handle controlled substances in the District of Columbia, the business address of the Respondent-pharmacy, or that the Respondent lacked a pharmacy license.

By order of March 7, 2002, the ALJ granted the Government's Motion, on the ground that DEA does not have statutory authority under the Controlled Substances Act to grant a registration if the applicant has no state authority to dispense controlled substances.

II. Final Order

The Acting Administrator adopts the ALJ's decision granting the Government's Motion, and all of the ALJ's prior decisions on motions in this matter. The Acting 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 of fact and conclusions.

As stated by the ALJ in her order granting the Government's motion, DEA has no authority to grant a registration if the registrant is without state authority to dispense controlled substances in the state in which the Respondent's business is located. 21 U.S.C. 823(f) and 824(a)(3): *See* Graham Travers Schuler, M.D., 65 FR 50,570 (DEA 2000); *see also* Saihb S. Halil, M.D., 64 FR 33,319 (DEA 1999); Greenbelt Professional Pharmacy, 57 FR 55,000 (DEA 1992).

Moreover, when there is not material questions of fact involved, or when the facts are agreed upon, there is no need