

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Timothy J. Irby/M.C.B.D. Pro International, TM Pure Dope Productions; Publishing Music Agency and Lab Research: Denial of Registration

On June 6, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mr. Timothy J. Irby and his business, which he identified as "M.C.B.D. Pro International; TM Pure Dope Productions; Publishing Music Agency and Lab Research" (MCBD) notifying Mr. Irby/MCBD of an opportunity to show cause as to why, pursuant to 21 U.S.C. 823(f) and 824(a), DEA should not deny the pending application for a DEA Certificate of Registration as a Researcher in Schedule I and II controlled substances. The Order to Show Cause alleged in relevant part that Mr. Irby and MCBD did not possess a State license to conduct research in controlled substances in Nevada, the State in which the applicant intended to conduct research and that registration would be inconsistent with the public interest.

The Order to Show Cause was sent by certified mail to Mr. Irby/MCBD at the registered location and last known address, identified in the application as 5450 Black Rock Way, Las Vegas, Nevada 89111-3705. This was Mr. Irby's residence. The Order to Show Cause was returned to DEA and the envelope marked by the United States Postal Service as "Moved. Left no address." NEA has no further information regarding the whereabouts of Mr. Irby/MCBD, nor any information from anyone purporting to represent them in this matter.

Therefore, the Acting Deputy Administrator of DEA, finding that: (1) 30 days having passed since the attempted delivery of the Order to Show Cause at Mr. Irby/MCBD's last known address, and (2) no requests for hearing having been received, concludes that Mr. Irby/MCBD are deemed to have waived their hearing rights. See *Kenneth S. Nave, M.D.*, 68 FR 24761 (2003); *Samuel S. Jackson, D.D.S.*, 67 FR 65145 (2002); *David W. Linder*, 67 FR 12579 (2002); *Lawrence C. Agee, M.D.*, 66 FR 52934 (2001). After considering material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Deputy Administrator's review of the investigative file reveals that on behalf of MCBD, Mr. Irby requested a DEA Certificate of Registration as a Researcher in schedule I and II controlled substances. The controlled substances identified in the application were cocaine, methamphetamine and marijuana. A DEA diversion investigator conducting a pre-registration investigation established that the intended place of registration was Mr. Irby's personal residence and that he does not possess a medical degree, any State licenses and was not affiliated with any medical facility, laboratory, clinic or staff.

Mr. Irby advised the DEA investigator he intended to conduct human research with the specified controlled substances. However, he has not obtained the required permissions to conduct human research from either the Food and Drug Administration or the State of Nevada, Health Division, Department of Licensure and Certification. Neither is Mr. Irby licensed with the Nevada State Board of Pharmacy or the Nevada Department of Health and Human Services nor does he possess a valid State business license.

In sum, the investigative file contains no evidence Mr. Irby/MCBD have personal licenses or affiliations with any legitimate medical or research facilities and have not taken even minimal steps to obtain requisite consents to conduct drug or human research in Nevada. Therefore, the Acting Deputy Administrator finds Mr. Irby/MCBD are not currently authorized to conduct research with controlled substances in the State of Nevada and it is reasonable to infer they are also without authorization to handle controlled substances in that State.

DEA does not have statutory authority under the Controlled Substances Act to issue a registration if the applicant is without State authority to handle controlled substances in the State in which he conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). The Acting Deputy Administrator and her predecessors have consistently so held. See *Douglas L. Geiger, M.D.*, 67 FR 64418 (2002); *Theodore T. Ambadgis, M.D.*, 58 FR 5759 (1993); *Ihsan A. Karqaagac, M.D.*, 51 FR 34695 (1986).

Considering the foregoing, the Acting Deputy Administrator concludes, pursuant to 21 U.S.C. 823(f), that Mr. Irby/MCBD lack authority under the laws of Nevada, the State of applied-for registration, to dispense or conduct research with respect to controlled substances and the application should be denied on that ground.

Because Mr. Irby/MCBD lack State authorization to handle controlled substances, the Acting Deputy Administrator concludes it is unnecessary to address whether or not his application for DEA registration should be denied based upon the public interest grounds asserted in the Order to Show Cause. See *Samuel Silas Jackson, D.D.S.*, 67 FR 65145 (2002); *Nathanial-Aikens-Afful, M.D.*, 62 FR 16871 (1997); *Sam F. Moore, D.V.M.*, 58 FR 14428 (1993).

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, submitted by Timothy J. Irby on behalf of M.C.B.D. Pro International, TM Pure Dope Productions, Publishing Music Agency and Lab Research, be, and it hereby is, denied. This order is effective March 8, 2004.

Dated: January 7, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Notice of Registration

By notice dated October 7, 2003, and published in the **Federal Register** on October 29, 2003 (68 FR 61700), ISP Freetown Fine Chemicals, 238 Main South Street, Assonet, Massachusetts 02702, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import Phenylacetone to manufacture amphetamine.

No comments or objections have been received. DEA has considered the factors in title 21, United States Code, section 823(a) and determined that the registration of ISP Freetown Fine Chemicals to import the listed controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated ISP Freetown Fine Chemicals on a regular basis to ensure that the company's continued