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.

[FR Doc. 04–2339 Filed 2–4–04; 8:45 am]

BILLING CODE 4410–09–M

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

registration is consistent with the public interest. This investigation included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. Therefore, pursuant to section 1008(a) of the Controlled Substances Import and Export Act and in accordance with Title 21, Code of Federal Regulations, section 1301.34, the above firm is granted registration as an importer of the basic classes of controlled substances listed.

Dated: December 24, 2003.

Laura M. Nagel,

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

[FR Doc. 04–2340 Filed 2–4–04; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–14]

Prescriptionline.com Revocation of Registration

On December 18, 2002, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Prescriptiononline.com (Respondent) of Las Vegas, Nevada. Relying on 21 U.S.C. 823(f) and 824(a)(3), (a)(4) and (d), the Order proposed revoking Respondent's retail pharmacy Certificate of Registration, BP6558069, and denying any pending applications for renewal or modification of such registration. It further notified Respondent that its registration was suspended immediately, that the suspension would remain in effect until a final determination in this proceeding and that DEA agents were authorized to and directed to place under seal and remove all controlled substances possessed by Respondent and take into their possession, Respondent's certificate of registration.

As grounds for revocation, the Order to Show Cause alleged, among other things, that between March 12 and September 26, 2002, Respondent provided 1,599,828 dosage units of controlled substances via the Internet pursuant to prescriptions issued by physicians who had not established physician-patient relationships with the persons to whom the prescriptions were issued.

On January 22, 2003, Respondent, through counsel, timely requested a hearing in this matter and on January 24, 2003, the Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued the Government, as well as Respondent, an Order for Prehearing Statements. On February 12, 2003, in lieu of filing a prehearing statement, the Government filed Government's Motion for Summary Judgment and to Extend the Time to File Prehearing Statements if Necessary. The Government argued Respondent had entered into a stipulation and agreement with the Nevada State Board of Pharmacy (Nevada Board) in which, among other things, Respondent agreed to revocation of its Nevada pharmacy license, that on January 27, 2003, the Nevada Board ratified the stipulation and agreement and that as a result, Respondent is no longer authorized to dispense or otherwise handle controlled substances in the State of Nevada, the jurisdiction in which it is registered, a prerequisite for DEA registration. Attached to the Government's motion was a copy of the stipulation and agreement and the Nevada Board's order ratifying it.

On February 14, 2003, Judge Bittner issued a Memorandum to Counsel and Order staying the filing of prehearing statements and providing Respondent until February 28, 2003, to respond to the Government's motion. Respondent did not file any response.

On March 19, 2003, Judge Bittner issued her Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Bittner granted the Government's Motion for Summary Disposition and found that Respondent lacked authorization to handle controlled substances in Nevada, the jurisdiction in which it was registered. Judge Bittner also recommended that the Respondent's DEA certificate of registration be revoked and that any pending applications for renewal or modification be denied. No exceptions were filed by either party to Judge Bittner's Opinion and Recommended Decision and on April 22, 2003, the record of these proceedings was transmitted to the Office of the then-DEA Deputy Administrator.

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

The Acting Deputy Administrator finds that Respondent, registered to do business in the State of Nevada, was issued DEA Certificate of Registration BP6558069 as a retail pharmacy. The Acting Deputy Administrator further finds that on January 22, 2003, Respondent voluntarily entered into a ''Stipulation and Agreement between Board Staff and Prescriptionline.com'' in which Respondent agreed to revocation of its State of Nevada pharmacy license. On January 27, 2003, the Nevada Board issued an Order ratifying the stipulation and agreement. Respondent has not denied that it currently is not licensed to practice pharmacy in Nevada, its jurisdiction of registration.

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 dispense or handle controlled substances in the State in which it conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See Karen Joe Smily, M.D.,* 68 FR 48944 (2003); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993); *Bobby Watts, M.D.,* 53 FR 11919 (1988); *Wingfield Drugs, Inc.,* 52 FR 27070 (1987).

Here, it is clear that Respondent is not currently licensed to handle controlled substances in Nevada, the jurisdiction in which it maintains a DEA registration. Therefore, it is not currently entitled to a DEA registation.

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 DEA Certificate of Registration issued to Prescriptionline.com be, and it hereby is, revoked. The Acting Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are, denied. This order is effecting March 8, 2004.

Dated: January 7, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 04–2342 Filed 2–4–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Notice of Registration

By notice dated September 2, 2003, and published in the **Federal Register** on October 27, 2003 (68 FR 61234–61235), Sigma Aldrich Company, Subsidiary of Sigma-Aldrich