

Dated: December 14, 1998.

John H. King,

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

[FR Doc. 98-33886 Filed 12-22-98; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 17, 1998, Eli-Elsohly Laboratories, Inc., Mahmoud A. Elsohly, PhD, 5 Industrial Park Drive, Oxford, Mississippi 38655, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Amphetamine (1100)	II
Methamphetamine (1150)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylcegonine (9180)	II
Hydrocodone (9193)	II

The firm plans to bulk manufacture non-deuterated controlled substances for use as analytical standards and deuterated controlled substances for use as internal standards.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than February 22, 1999.

Dated: December 14, 1998.

John H. King,

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

[FR Doc. 98-33881 Filed 12-27-98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 12, 1998, High Standard Products, 1100 W. Florence Avenue, #B, Inglewood, California 90301, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370) ..	I
3,4-Methylenedioxyampheta- mine (7400)	I
3,4-Methylenedioxy-N- ethylamphetamine (7404)	I
3,4-Methylenedioxy- m- thamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
Heroin (9200)	I
3-Methylfentanyl (9813)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Secobarbital (2315)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Morphine (9300)	II
Fentanyl (9801)	II

The firm plans to manufacture analytical reference standards.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections 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 February 22, 1999.

Dated: December 2, 1998.

John H. King,

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

[FR Doc. 98-33889 Filed 12-23-98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on August 4, 1998, Irix Pharmaceuticals, Inc., 101 Five Star Way, Florence, South Carolina 29501, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of methylphenidate (1724), a basic class of controlled substance listed in Schedule II.

The firm place to manufacture methylphenidate for demonstration purposes and for dosage form development and stability studies.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the proposed registration.

Any such comments or objections 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 Representatives (CCR), and must be filed no later than February 22, 1999.

Dated: December 10, 1998.

John H. King,

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

[FR Doc. 98-33882 Filed 12-22-98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 97-25]

Mary M. Miller, M.D.; Grant of Restricted Registration

On July 8, 1997, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mary Margaret Miller, M.D. (Respondent) of Louisville, Kentucky, notifying her of an opportunity to show cause as to why DEA should not deny her application for registration as a practitioner pursuant to 21 U.S.C. 823(f) and 824(a)(2).

By letter dated July 16, 1997, Respondent requested a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held in Frankfort, Kentucky on December 10, 1997, before Administrative Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. On June 25, 1998, Judge Randall issued her Opinion and Recommended Ruling, recommending that Respondent be granted a DEA Certificate of Registration subject to several conditions. Neither party filed exceptions to the Opinion and Recommended Ruling of the Administrative Law Judge and on July 28, 1998, Judge Randall transmitted the record of these proceedings to the then-Acting Deputy Administrator.

The 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 Deputy Administrator adopts the Opinion and Recommended Ruling of the Administrative Law Judge, but includes an additional condition on Respondent's registration. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact of law.

The Deputy Administrator finds that Respondent graduated from medical school in 1962 and obtained her first DEA registration in approximately 1963 while practicing in Colorado. In 1981, Respondent also became licensed to practice medicine in Kentucky.

In 1983, DEA noted that pharmacies in the Fort Collins, Colorado area were ordering large quantities of Schedule II controlled substances. Further investigation revealed that Respondent's name repeatedly came up as a large prescriber of Schedule II substances. As a result, DEA initiated an investigation of Respondent. An undercover DEA agent went to Respondent's office on five occasions to attempt to obtain controlled substance prescriptions for no legitimate medical purposes.

The first undercover operation was conducted on August 16, 1983, during which the undercover agent received prescriptions for Biphedamine and Seconal, both Schedule II controlled substances, from Respondent. Initially, the undercover agent told Respondent that she needed to lose weight, but later stated that she was a prostitute and that she needed Biphedamine to stay up all night and Seconal to allow her to sleep during the day. Respondent did not perform any physical examination and told the undercover agent not to fill the prescriptions in the Fort Collins area. Neither Biphedamine nor Seconal were acceptable for weight loss treatment in Colorado in 1983. Respondent later said that the prescribed substances were for narcolepsy and narcolepsy was noted on the prescriptions. However, there was no discussion regarding narcolepsy during this visit.

The undercover agent returned to Respondent's office on August 23, 1983, however she was unable to see Respondent on that day. The third undercover operation was conducted on September 15, 1983, during which the undercover agent obtained prescriptions from Respondent for Biphedamine, Seconal and Valium, a Schedule IV controlled substance. The undercover agent received the prescription for Valium after telling Respondent that she needed something to "smooth her out" between the Biphedamine and the Seconal. The undercover agent did not assert any medical complaints during this visit.

The undercover agent returned to Respondent's office on October 4, 1983. She obtained prescriptions for Biphedamine, Seconal and Valium from Respondent even though she did not give any medical reasons for needing the drugs. Respondent told the undercover agent to fill the prescriptions at different pharmacies

and not to fill them at pharmacies in Fort Collins.

The final visit occurred on November 1, 1983, during which the undercover agent again obtained prescriptions for Biphedamine, Seconal and Valium from Respondent without giving any medical reason. Respondent again told the undercover agent not to have the prescriptions filled in Fort Collins. On this occasion the undercover agent asked for a prescription for another amphetamine and also asked for a prescription for a friend. Respondent refused both of these requests.

As a result of this investigation, Respondent was ultimately convicted on October 22, 1984, in the United States District Court of Colorado of 15 counts of distribution of controlled substances and prescriptions not issued for a legitimate medical purpose in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). Respondent was sentenced to 30 months imprisonment followed by 5 years probation and fined \$75,000. She served 10 months in prison during which time she inactivated her Kentucky medical license.

As a result of her conviction, in October 1984 the Colorado Board of Medical Licensure (Colorado Board) suspended her medical license. Her license was reinstated in 1986.

According to Respondent, she abused alcohol during her criminal trial and again after her release from prison. After being confronted by her family about her alcohol abuse she entered an inpatient treatment facility for three months. Respondent testified that she has not consumed any alcohol since January 29, 1990. While in treatment, the Colorado Board suspended her medical license and on September 28, 1990, Respondent's Colorado medical license was revoked based upon her "habitual intemperance", referring to her abuse of alcohol.

Thereafter, Respondent applied for reinstatement of her Kentucky medical license which was denied by the Kentucky Board of Medical Licensure (Kentucky Board) in November 1992. The Kentucky Board recommended that Respondent get involved with the Kentucky Impaired Physicians Program (Kentucky Program). Respondent became involved with the Kentucky Program in 1993 and was required to attend four to six Alcoholics Anonymous (AA) meetings per week.

In December 1992, Respondent also became involved with an outpatient facility that treats alcohol and drug addiction. Respondent participated in the physicians' therapy group for approximately two years and agreed to