University of Louisville and by working at the family health care clinics since 1996. However, as Judge Randall noted, ''since she has not been registered by the DEA to handle controlled substances for the past fifteen years she has lacked the opportunity to demonstrate that she can responsibly handle controlled substances.''

Regarding factor three, it is undisputed that in 1984, Respondent was convicted in the United States District Court for the District of Colorado of 15 counts of distributing controlled substances and issuing prescriptions for other than a legitimate medical purpose in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04.

As to factor five, the Deputy Administrator is concerned with Respondent's history of alcohol abuse. However, Respondent's sobriety date is Janaury 29, 1990. In addition, she has taken tremendous steps toward rehabilitating herself, and there was credible evidence presented at the hearing that Respondent is unlikely to relapse if she continues to attend to her recovery.

The Deputy Administrator concludes that Respondent's actions in 1983 were clearly contrary to the public interest and raise serious concerns regarding her fitness to be registered with DEA. However, the Deputy Administrator finds that there is evidence in the record that supports granting Respondent's application. Respondent's criminal conduct occurred 15 years ago. As has been previously determined, ''[t]he paramount issue is not how much time has elapsed since [Respondent's] unlawful conduct, but rather, whether during that time Respondent has learned from past mistakes and has demonstrated that [she] would handle controlled substances properly if entrusted with DEA registration.'' *Leonardo V. Lopez, M.D.,* 54 FR 36,915 (1989). Here, the Deputy Administrator finds it significant that Respondent has accepted responsibility for her past misconduct and fully disclosed her history on her application for registration. In addition, she has recently participated in a family practice residency program and has continued to practice medicine at the family health care clinics in Kentucky. Also, if granted a DEA registration, Respondent's controlled substance prescribing will be monitored by the Kentucky Board.

Concerning her alcoholism the Deputy Administrator agrees with Judge Randall's finding ''that the significant steps the Respondent has taken to rehabilitate herself demonstrate her commitment to her continuing recovery and to her profession.'' The Deputy Administrator also finds it noteworthy that according to the medical director of the Kentucky Impaired Physicians Program, the chance of Respondent relapsing is 90–95% if she continues with her recovery efforts.

Therefore, the Deputy Administrator agrees with Judge Randall's conclusion that Respondent should be given the opportunity to demonstrate that she can responsibly handle controlled substances. But in order to protect the public health and safety, some controls are warranted given her illegal prescribing of controlled substances, her conviction and her alcohol abuse. Imposing controls upon Respondent's registration ''will allow the Respondent to demonstrate that [she] can responsibly handle controlled substances in [her] medical practice, yet simultaneously protect the public by providing a mechanism for rapid detection of any improper activity related to controlled substances.'' *Steven M. Gardner, M.D.,* 51 FR 12,576 (1986), as cited in *Michael J. Septer, D.O.,* 61 FR 53,762 (1996).

Judge Randall recommended that Respondent's application be granted, provided that for three years Respondent must provide the local DEA office with a log of her controlled substance handling; she must maintain her contractual relationship with the Kentucky Impaired Physicians Program; and she must inform DEA of any action taken by any state upon her license or authorization to practice medicine or handle controlled substances. The Deputy Administrator agrees with Judge Randall's recommended restrictions, but concludes that Respondent should also be required to consent to periodic inspections by DEA without requiring an Administrative Inspection Warrant.

Therefore, the Deputy Administrator concludes that Respondent's application for registration in Schedules III, IIIN, IV and V should be granted subject to the following restrictions for three years from the date of issuance of the DEA Certificate of Registration:

1. On a quarterly basis, Respondent must provide the DEA Louisville Resident Office with a log, which at a minimum, should indicate: (1) the date that the controlled substance prescription was written, or such substance was administered or dispensed; (2) the name of the patient for whom the prescription was written, or to whom the substance was dispensed or administered; (3) the patient's complaint; (4) the name, dosage, and quantity of the substance prescribed, dispensed or administered; and (5) the date that the medication was last prescribed, dispensed or administered to that patient, as well as the amount last provided to that patient.

2. Respondent must maintain her contractual relationship with the Kentucky Impaired Physicians Program and abide by their recommendations.

3. Within 30 days, Respondent must inform the DEA Louisville Resident Office of any action taken by any state upon her medical license or upon her authorization to handle controlled substances.

4. Respondent shall consent to periodic inspections by DEA personnel based on a Notice of Inspection rather than an Administrative Inspection Warrant.

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 May 1, 1995 application for registration in Schedules III, IIIN, IV and V submitted by Mary M. Miller, M.D., be, and it hereby is, granted subject to the above described restrictions. This order is effective no later than January 21, 1999.

Dated: December 16, 1998.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 98–33890 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 October 26, 1998, Noramco of Delaware, Inc., Division of McNeilab, Inc., 500 Old Swedes Landing Road, Wilmington, Delaware 19801, 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
Codeine (9050)	II
Oxycodone (9143)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Thebaine (9333)	II

The firm plans to manufacture the listed controlled substances for distribution to its customers as bulk product.

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 14, 1998.

John H. King,

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

[FR Doc. 98–33883 Filed 12–22–98; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated June 15, 1998, and published in the **Federal Register** on September 3, 1998, (63 FR 47040), Organix, Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of cocaine, a basic class of controlled substance listed in Schedule II.

The firms plans to manufacture a derivative of cocaine in grant quantities for validation of synthetic procedures.

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 Organix, Inc. to manufacture cocaine is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. § 823 and 28 C.F.R. §§ 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: December 11, 1998.

John H. King,

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

[FR Doc. 98–33887 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 August 6, 1998, Pressure Chemical Company, 3419 Smallman Street, Pittsburgh, Pennsylvania 15201, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of 2,5-dimethoxyamphetamine (7396), a basic class of controlled substance listed in Schedule I.

The firm plans to bulk manufacture 2,5-dimethoxyamphetamine for distribution to its customers.

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 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. 98–33884 Filed 12–22–98; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA # 179I]

Controlled Substances: Established Initial Aggregate Production Quotas for 1999

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 1999.

SUMMARY: This notice establishes initial 1999 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: December 23, 1998.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by Section 0.100 of Title 28 of the Code of Federal Regulations. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to Section 0.104 of Title 28 of the Code of Federal Regulations.

The 1999 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 1999 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. 826(a) and 21 CFR 1303.11). These quotas do not include imports of controlled substances for use in industrial processes.

On October 16, 1998, a notice of the proposed initial 1999 aggregate production quotas for certain controlled substances in Schedules I and II was published in the **Federal Register** (63 FR 55640). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before November 16, 1998.

Nine companies commented on a total of 28 Schedules I and II controlled substances. The companies commented that the proposed aggregate production quotas for 2,5-dimethoxyamphetamine, 4-methoxyamphetamine, alfentanil, amphetamine, codeine (for sale), codeine (for conversion), dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone (for sale), hydrocodone (for conversion), hydromorphone, levorphanol, meperidine, methadone (for sale), methadone (for conversion), methadone intermediate, methylphenidate, morphine (for sale), morphine (for conversion), oxycodone (for sale), oxycodone (for conversion), pentobarbital, propiram, secobarbital, sufentanil and thebaine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks. In addition, one company commented that the initial