Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 27, 1996, 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
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxymeth-amphetamine (7405).	I
4-Methoxyamphetamine (7411)	I
1-(1-Phenylcyclohexyl) pyrrolidine (7458).	I
Heroin (9200)	I
Normorphine (9313)	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
Benzoylecgonine (9180)	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 above application.

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, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than February 24, 1997.

Dated: November 18, 1996.

Gene R. Haislip,

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

[FR Doc. 96–32611 Filed 12–23–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 26, 1996, and published in the Federal Register on March 4, 1996 (61 FR 8303), Johnson Matthey, Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances listed below:

Drug	Schedule
2,5-Dimethoxyamphetamine (7396)	I
Difenoxin (9168)	I
Methylphenidate (1724)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Meperidine intermediate-C (9234)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Fentanyl (9801)	II

Also, by notice dated April 3, 1996, and published in the Federal Register on April 10, 1996, Johnson Matthey made application to be registered as a bulk manufacturer of dihydrocodeine (9120) and by notice dated May 28, 1996 and published in the Federal Register on June 5, 1996 Johnson Matthey made application to be registered as a bulk manufacturer of thebaine (9333) and alfentanil (9737).

Three registered manufacturers of bulk controlled substances filed comments in response to the notice of application. The first commentor filed comments with respect to codeine, oxycodone, hydrocodone and morphine, and the second commentor with respect to codeine, oxycodone, hydocodone, morphine, dihydrocodeine, oxymorphone and thebaine. The third commentor filed comments with respect to methylphenidate.

The first and second commentors argued against approval of Johnson Matthey's application for the seven opiates (hereafter referred to as the opiates) because Johnson Matthey's registration could trigger a shortage of narcotic raw materials (NRM), that the ''80/20 Rule'' would be negatively impacted and that Johnson Matthey does not have the NRM importation and extraction experience needed to efficiently manufacture the opiates from NRMs.

These arguments are based on the assumption that Johnson Matthey will import NRMs to manufacture the opiates. However, Johnson Matthey has not made application to import NRMs or manufacture the opiates from NRMs. Investigation by DEA has determined that the firm will not bulk manufacture codeine and morphine and plans to use domestic sources to obtain the materials needed to manufacture the remaining opiates. Therefore, these comments would appear to be moot.

The first commentor further argues that Johnson Matthey should be registered because it would increase regulatory costs and that the current manufacturers are providing an adequate supply. The commentor also offers in evidence that as a result of hearing with respect to Johnson Matthey's 1992 application to bulk manufacture methylphenidate, the Administrative Law Judge (ALJ) concluded that Johnson Matthey's experience in manufacturing methylphenidate under a researcher registration presented a ''sorry history of evasion and/or outright violations of DEA regulations''.

The second commentor also argues against approval of Johnson Matthey's application citing the ALJs findings in the methylphenidate hearings. Also, this commentor argues that Johnson Matthey has a huge capability and experience gap that encompasses technical expertise, experienced personnel, research knowledge, security and compliance commitment.

Both the first and second commentors use the findings of the ALJ in support of their arguments that Johnson Matthey's application be denied. Nevertheless, the ALJ did conditionally approve Johnson Matthey's application to bulk manufacture methylphenidate and in a subsequent Federal Register notice dated September 4, 1996 (61 FR 46664), terminated all proceedings with respect to JM's application to bulk manufacture methylphenidate.

With respect to the first commentor's contention that another manufacturer is not needed because there is a current and adequate supply, the Controlled Substances Act (CSA) does not demand that such a finding be made before the Drug Enforcement Administration (DEA) can register a bulk manufacturer.

Furthermore, pursuant to 21 CFR 1301.43(b), DEA is not required to limit the number of manufacturers in any basic class to a number less than that

consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

DEA is confident that the registration of Johnson Matthey will not impede DEA's statutory obligation to guard against the diversion of controlled substances.

Also, with respect to the second commentor's allegation that John Matthey has a huge capability and experience gap, Johnson Matthey has been registered with DEA since 1985. In the past 11 years, Johnson Matthey has demonstrated its technical and manufacturing expertise with respect to other controlled substances. Based on this history and recent investigation, DEA is confident that Johnson Matthey will continue this practice with respect to the opiates.

Additionally, DEA has investigated Johnson Matthey on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. The results of these investigations have led DEA to conclude that Johnson Matthey is in compliance with the CSA and that its continued registration is consistent with the public interest.

The third commentor states that there is sufficient information to show that the registration of Johnson Matthey to bulk manufacture methylphenidate is not in the public interest and an order to show cause be issued to deny Johnson Matthey's application. However, in Federal Register notice 61 FR 46664 (September 4, 1996), it was ordered that a request for a hearing concerning Johnson Matthey's February 1995, registration application and the proceedings following and relevant to that request be, and they hereby are, terminated. Since the ALJ approved Johnson Matthey's 1992 application to bulk manufacture methylphenidate on September 29, 1994, as a result of a previous hearing and the hearing request for the 1995 application was terminated, DEA finds no basis for yet another hearing to deny Johnson Matthey's application to bulk manufacture methylphenidate.

After reviewing all the evidence, including the comments filed, DEA has determined, pursuant to 21 U.S.C. 823(a), that registration of Johnson Matthey as a bulk manufacturer of oxycodone, hydrocodone, dihyrocodeine, oxymorphone, thebaine and methylphenidate is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator hereby orders that the 1996 applications submitted by Johnson Matthey for registration as a bulk manufacturer of the listed controlled substances, excluding codeine and morphine, but including oxycodone, hydrocodone, dihydrocodeine, oxymorphone, thebaine and methylphenidate are granted.

Dated: December 12, 1996.

Gene R. Haislip,

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

[FR Doc. 96–32612 Filed 12–23–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 21, 1996, and published in the Federal Register on September 5, 1996, (61 FR 46827), Noramco of Delaware, Inc., Division of McNeilab, Inc., 500 Old Swedes Landing Road, Wilmington, Delaware 19801, made application for 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

By a Notice of Correction dated October 21, 1996, and published in the Federal Register on November 14, 1996, (61 FR 58424), fentanyl was deleted from Noramco of Delaware, Inc.'s application for bulk manufacture.

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 Noramco of Delaware, Inc. to manufacture the listed controlled substances 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 classes of controlled substances listed above is granted, except for fentanyl.

Dated: December 5, 1996.

Gene R. Haislip,

Deputy Assistant Administrator Office of Diversion Control Drug Enforcement Administration.

[FR Doc. 96–32606 Filed 12–23–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 2, 1996, Radian International LLC, 8501 North Mopac Blvd., P.O. Box 201088, Austin, Texas 78720, made application by letter dated October 2, 1996, to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Alpha-Ethyltryptamine (7249)	I
3,4,5-Trimethoxyamphetamine (7390)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
Bufotenine (7433)	I
Codeine-N-oxide (9053)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Pholcodine (9314)	I
Alphamethadol (9605)	I
Betcetylmethadol (9607)	I
Betamethadol (9609)	I
Norlevorphanol (9634)	I
Para-Fluorofentanyl (9812)	I
Alpha-methylfentanyl (9814)	I
Acetyl-alpha-methylfentanyl (9815)	I
Beta-hydroxyfentanyl (9830)	I
Beta-hydroxy-3-methylfentanyl (9831)	I
Alpha-Methylthiofentanyl (9832)	I
3-Methylthiofentanyl (9833)	I
Thiofentanyl (9835)	I
Phenmetrazine (1631)	II
Glutethimide (2550)	II
Cocaine (9041)	II
Codeine (9050)	II
Levomethorphan (9210)	II