## 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.*

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## 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