

licensing reveals that the granting or denial of a manufacturer's registration is a licensing action, not a rulemaking. Courts have frequently distinguished between agency licensing actions and rulemaking proceedings. See, e.g. *Gateway Transp. Co. v. United States*, 173 F. Supp. 822, 828 (D.C. Wis. 1959); *Underwater Exotics, Ltd. v. Secretary of the Interior*, 1994 U.S. Dist. LEXIS 2262 (1994). Courts have interpreted agency action relating to licensing as not falling within the APA's rulemaking provisions.

The objector argues that Nycomed cannot prove its registration as a bulk manufacturer of methylphenidate is in the public interest, that Nycomed's registration is not required to produce an adequate and uninterrupted supply of methylphenidate, that there is sufficient competition with the present bulk manufacturers and that by there would be a public interest impact on reported trends of over-prescribing, abuse and diversion of methylphenidate.

The arguments of the objector were considered, however, DEA has reviewed the firm's safeguards to prevent the theft and diversion of methylphenidate and found that the firm has met the regulatory requirements and public interest factors of the Controlled Substances Act.

Nycomed has been and is currently registered with DEA as a manufacturer of other Schedule II controlled substances. Nycomed's application is based on the firm's request to add methylphenidate to its existing registration as a bulk manufacturer. The firm has been investigated by DEA on a regular basis to determine if the firm maintains effective controls against diversion and if its continued registration is consistent with the public interest. These investigations have included, in part, inspection and testing of the firm's physical security, audits of the firm's records, verification of compliance with state and local law and a review of the firm's background and history. These investigations have found Nycomed to be in compliance with the Controlled Substances Act (C.S.A.) and its implementing regulations in recent years.

Under Title 21, Code of Federal Regulations, Section 1301.43(b), DEA is not required to limit the number of manufacturers solely because a smaller number is capable of producing an adequate supply provided effective controls against diversion are maintained. DEA has determined that effective controls against diversion will be maintained by Nycomed.

Additionally, Nycomed has applied for registration as a bulk manufacturer in order to perform a chemical isolation process on methylphenidate which had been manufactured by another manufacturer currently registered to bulk manufacture methylphenidate.

After reviewing all the evidence, DEA has determined, pursuant to 21 U.S.C., Section 823(a) that it is consistent with the public interest to grant Nycomed's application to manufacture methylphenidate at this time. Therefore, pursuant to 21 U.S.C. Section 823 and 28 CFR Section 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: July 29, 1998.

**John H. King,**

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

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Importer of Controlled Substances; Notice of Registration**

By Notice dated May 7, 1998, and published in the **Federal Register** on May 19, 1998 (63 FR 27590), Roche Diagnostic Systems, Inc., 1080 U.S. Highway 202, Somerville, New Jersey 08876-3771, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of tetrahydrocannabinols (7370), a basic class of controlled substance listed in Schedule I.

The tetrahydrocannabinols will be utilized exclusively for non-human consumption in drug of abuse detection kits.

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 Roche Diagnostic Systems to import tetrahydrocannabinols 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. 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 class of controlled substance listed above.

Dated: July 17, 1998.

**John H. King,**

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

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Importer of Controlled Substances Notice of Registration**

By Notice dated May 4, 1998, and published in the **Federal Register** on May 19, 1998, (63 FR 27591), Sigma Chemical Company, Subsidiary of Sigma-Aldrich Company, 3500 Dekalb Street, St. Louis, Missouri 63118, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed below:

Drug	Schedule
Cathinone (1235) .....	I
Methcathinone (1237) .....	I
Methaqualone (2565) .....	I
Ibogaine (7260) .....	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370) .....	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxy-methamphetamine (7405).	I
4-Methoxyamphetamine (7411) ....	I
Psilocyn (7438) .....	I
Normorphine (9313) .....	I
Amphetamine (1100) .....	II
Methamphetamine (1105) .....	II
Methylphenidate (1724) .....	II
Amobarbital (2125) .....	II
Pentobarbital (2270) .....	II
Secobarbital (2315) .....	II
Phencyclidine (7471) .....	II
Cocaine (9041) .....	II
Codeine (9050) .....	II
Oxycodone (9143) .....	II
Hydromorphone (9150) .....	II
Benzoyllecgonine (9180) .....	II
Ethylmorphine (9190) .....	II
Hydrocodone (9193) .....	II
Levorphanol (9220) .....	II
Meperidine (9230) .....	II
Methadone (9250) .....	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300) .....	II
Thebaine (9333) .....	II
Opium powdered (9639) .....	II
Oxymorphone (9652) .....	II
Fentanyl (9801) .....	II