

Dated: March 1, 1999.

John H. King,

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

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John H. King,

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

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John H. King,

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 14, 1998, and published in the **Federal Register** on December 23, 1998 (63 FR 71159), 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) to be registered 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.

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. DEA has investigated Noramco of Delaware, Inc. 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. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 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.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 1, 1998, and published in the **Federal Register** on October 9, 1998, (63 FR 54492), Nycomed, Inc., 33 Riverside Avenue, Rensselaer, New York 12144, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Methylphenidate (1724)	II
Meperidine (9230)	II

The firm plans to manufacture meperidine as bulk product for distribution to its customers and to perform a chemical isolation process on methylphenidate which has been manufactured by another bulk manufacturer of methylphenidate.

DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Nycomed, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Mycomed, Inc. 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. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 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.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Prodim Denial of Application

On June 5, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Prodim (Respondent) proposing to deny its application for registration as an exporter of Schedule II, III and IV controlled substances under 21 U.S.C. 958, for reason that its registration would be inconsistent with the public interest pursuant to 21 U.S.C. 823 (a) and (b).

The Order to Show Cause was ultimately received by Randall Tetzner who signed the application for registration on behalf of Respondent. By letter dated September 4, 1998, Respondent waived its opportunity for a hearing and instead submitted a written statement pursuant to 21 CFR 1301.43(c).

Therefore, the Deputy Administrator concludes that Respondent has waived its opportunity for a hearing and hereby enters his final order in this matter based upon the investigative file and Respondent's written statement pursuant to 21 CFR 1301.43 (c) and (e) and 1301.46.

The Deputy Administrator finds that Randall Tetzner, on behalf of Respondent, submitted an application dated October 7, 1995, for registration with DEA as an exporter of Schedule II, III and IV controlled substances. According to Mr. Tetzner, Respondent wants to be registered in order to send donated or purchased controlled substances to Honduras. In describing Respondent, Mr. Tetzner stated that "[t]he organization I volunteer with and work with supplies needed medications to rural villages in Honduras. * * * From a base camp in La Paz, a worker brings replacement medications via motorcycle to the villages."

After numerous discussions and correspondence between DEA and Mr. Tetzner, an Order to Show Cause was issued on June 5, 1998, proposing to deny Respondent's application for registration. Specifically, the Order to Show Cause alleges that Respondent's registration would be inconsistent with