Dated: March 1, 1999.

John H. King,

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

[FR Doc. 99–7939 Filed 3–31–99; 8:45 am]

BILLING CODE 4410–09–M

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.

Dated: March 17, 1999.

John H. King,

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

[FR Doc. 99–7940 Filed 3–31–99; 8:45 am]

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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 it 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.

Dated: March 1, 1999.

John H. King,

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

[FR Doc. 99–7941 Filed 3–31–99; 8:45 am]

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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

the public interest based upon the following:

a. Mr. Tetzner is the sole representative of Prodim. On the application for DEA registration he provided as an address his trailer home. This location does not have secure controlled substance storage facilities and Prodim does not have an alternative location with which to securely store controlled substances, as required by 21 CFR § 1301.72. Therefore, Mr. Tetzner has not demonstrated that he can maintain effective controls against the diversion of controlled substances as required pursuant to 21 U.S.C. § 823(a)(1).

b. In a letter to DEA dated February 15, 1996, Mr. Tetzner, informed DEA that he had never before exported controlled substances. Therefore, Prodim has no experience in the export of controlled substances. 21 U.S.C. § 958(a) and § 823(a)(5) and (d)(5).

In his written statement dated September 4, 1998, Mr. Tetzner indicated that he never meant to store controlled substances at his home, but instead proposed that Respondent would ''give DEA at least 30 days notice of our intent to send the medications, we purchase or recieve [sic] the medications at a hospital or drug company, then while on site we do the required paperwork and on site we ship the medications pursuant [sic] to DEA directives. * * * The medications would only go from an already registered facility, be transferred via paperwork, then the donating agency would then confirm the transfer and they would ship the drugs. In no manner shall PRODIM ever possess these drugs other than to count and verify on site.'' Further, Mr. Tetzner indicated that he has been a paramedic for a number of years and as such understands the importance of documenting the use of controlled substances.

Pursuant to 21 U.S.C. 958 and 823, the Deputy Administrator may deny an application for registration as an exporter of controlled substances if he finds that such registration would be inconsistent with the public interest. In determining the public interest, the Deputy Administrator shall consider the factors set forth in 21 U.S.C. 823(a) for registration to export Schedule II controlled substances and the factors set forth in 21 U.S.C. 823(d) for registration to export Schedule III and IV controlled substances. The factors in these two sections are essentially the same. Pursuant to 21 U.S.C. 823(d), the Deputy Administrator shall consider:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substances in Schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
(2) Compliance with applicable State and local law;
(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;
(4) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
(5) Past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
(6) Such other factors as may be relevant to and consistent with the public health and safety.

The Deputy Administrator finds that there is no evidence in the record regarding factors two, three or four. Regarding factor one, there is very little specific evidence in the record as to the controls Respondent will maintain against the diversion of controlled substances. In its written statement, Respondent maintains that it will not take possession of the controlled substances; that the substances would be sent from a location already registered with DEA, that the donating agency would confirm the transfer and ship the rugs, and that Respondent will only count and verify the drugs on site.

Pursuant to 21 CFR 1301.43(c), a written statement ''shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.'' The Deputy Administrator finds that the assertions in Respondent's written statement warrant little weight. The Deputy Administrator is unable to determine from Respondent's written statement who would be responsible for the controlled substances since the controlled substances would be stored at the donating agency and the donating agency would confirm the transfer and ship the drugs. Further, the Deputy Administrator is unable to determine what controls against diversion would be in place during the shipment of any controlled substances. Of even greater concern is that the Deputy Administrator is unable to determine from Respondent's written statement the identity or location of the donating agency or agencies, and is therefore unable to determine whether effective controls are maintained to prevent the diversion of exported controlled substances.

Regarding factor five while Mr. Tetzner indicates that he has handled controlled substances as a paramedic and a Navy corpsman, there is no evidence that he has any experience in exporting controlled substances, nor in the responsibilities of a DEA registrant in preventing the diversion of controlled substances.

As to factor six, the record indicates that Respondent and Mr. Tetzner do not have sufficient knowledge and understanding of the export requirements set forth in 21 U.S.C. 953 and 21 CFR 1312.21. In Respondent's written statement, Mr. Tetzner states that it will ''give the DEA at least 30 days notice of our intent to send the medications. * * *'' Respondent does not discuss whether its proposed exportations would meet the requirements of 21 U.S.C. 953, nor does it indicate that it will follow the procedures set forth in 21 CFR 1312.21 regarding obtaining the authorization to export specific shipments. Particularly troubling to the Deputy Administrator is that the record indicates that Mr. Tetzer was advised by DEA on several occasions of these requirements and was told where he could obtain a copy of the regulations, yet he did not do so.

The Deputy Administrator concludes that based upon the record currently before him Respondent's registration as an exporter of controlled substances would be inconsistent with the public interest. There is no evidence that Respondent would maintain effective controls against the diversion of controlled substances; that Respondent possesses relevant experience in the handling of controlled substances; and that Respondent understands the export requirements set forth in 21 U.S.C. 953 and 21 CFR 1312.21.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration pursuant to the authority vested in him by 21 U.S.C. 823 and 958 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for registration submitted by Prodim, be, and it hereby is, denied. This order is effective May 3, 1999.

Dated: March 15, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99–7929 Filed 3–31–99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and