is sufficient evidence in the record to conclude that Respondent, given the opportunity, will utilize a DEA registration in a responsible and professional manner.

The Administrator does impose the following restrictions upon the DEA registration in Schedules III, IV and V to be issued to Respondent:

1. Respondent shall keep a record of all controlled substances that he prescribes, administers, and/or dispenses in the course of any medical practice in which he might engage. The record must include the date, name of the patient, name and quantity of the controlled substance which was prescribed, administered or dispensed. Respondent shall send that record to the DEA San Francisco Field Division on a monthly basis for a period of three years.

2. Respondent must permit DEA personnel to conduct inspections at his place of business at any time during regular business hours for the purpose of evaluating his compliance with the Federal laws and regulations relating to controlled substances. Respondent must consent in writing that DEA personnel may enter his office or other place of practice without notice and without the presentation of any type of warrant.

Respondent's failure to comply with the foregoing terms, or his violation of any Federal or state law relating to controlled substances, shall constitute additional grounds for the revocation of his registration.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that the application for DEA registration submitted by Chester J. Hurd, M.D., on August 3, 1988, be granted in Schedules III, IV and V, subject to the restrictions enumerated above. The said registration shall be issued upon Respondent's execution of an agreement acknowledging and accepting the terms of this order.

Dated: February 5, 1990.

John C. Lawn,

Administrator.

[FR Doc. 90-3051 Filed 2-8-90; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Application

Pursuant to Section 1301.43(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on September 27, 1989, Johnson Matthey, Inc. Custom Pharmaceuticals Department, 2002 Nolte Drive, West Deptford, NJ 08066, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Pethidine (meperidine) (9230)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

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 and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA **Federal Register** Representative (CCR), and must be filed no later than March 12, 1990.

Dated: January 30, 1990.

Gene R. Haislip,

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

[FR Doc. 90-3047 Filed 2-8-90; 8:45 am]

BILLING CODE 4410-09-M

Importation of Controlled Substances; Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1311.42 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on December 7, 1989, Minn-Dak Growers Limited, Highway 81 North, P.O. Box 1276, Grand Forks, North Dakota 58206-1276, made application to the Drug Enforcement Administration to be registered as an importer of Marijuana (7360), a basic class of controlled substance in Schedule I. This application is exclusively for the importation of marijuana seed which will be rendered non-viable and used as bird seed.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, Federal Register Representative (CCR), and must be filed no later than March 12, 1990.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42 (b), (c), (d), (e) and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42 (a), (b), (c), (d), (e) and (f) are satisfied.

Dated: January 30, 1990.

Gene R. Haislip,

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

[FR Doc. 90-3050 Filed 2-8-90; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Application

Pursuant to section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on December 11, 1989, M.D. Pharmaceutical, Inc., 3501 West Garry Avenue, Santa Ana, California 92704, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Diphenoxylate (9170)	II
Methylphenidate (1724)	II

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 and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than March 12, 1990.

Dated: January 30, 1990.

Gene R. Haislip,

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

[FR Doc. 90-3048 Filed 2-8-90; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 87-76]

Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy; Revocation of Registration

On October 27, 1987, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Ralph J. Bertolino d/b/a Ralph J. Bertolino Pharmacy (Respondent), 1500 S. 12th Street, Philadelphia, Pennsylvania 19147, proposing to revoke DEA Certificate of Registration AB2343503, and to deny any pending applications for renewal of that registration. The Order to Show Cause alleged that the pharmacy's continued registration with DEA was inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f).

Respondent, through counsel, requested a hearing in a letter dated November 20, 1987. The matter was docketed before Administrative Law Judge Mary Ellen Bittner. Following prehearing procedures, a hearing was held in Washington, DC, on April 6 and 7, 1988. On March 8, 1989, the administrative law judge issued her opinion and recommended ruling. On May 15, 1989, counsel for Respondent filed exceptions to the administrative law judge's opinion, and on June 5, 1989, Government counsel filed a response to Respondent's exceptions. On July 20, 1989, Judge Bittner transmitted a record of these proceedings, including the aforementioned exceptions and response, to the Administrator. The Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues his final order in this matter based upon the findings of fact and conclusions of law as hereinafter set forth.

The Administrator finds that Ralph J. Bertolino, Sr., has been the owner and registered pharmacist at Ralph J. Bertolino Pharmacy since 1961. A 1985 DEA ARCOS report listed the pharmacy as the ninth highest purchaser of Preludin (phenmetrazine) in the State of Pennsylvania and the eleventh highest purchaser of Preludin in the United States. In 1986, the ARCOS report listed Respondent pharmacy as the tenth highest purchaser of Preludin in Pennsylvania and in the United States.

In response to a serious problem with the diversion of stimulants in the State of Pennsylvania, the Philadelphia Office of the DEA undertook a project called Operation Quaker State which involved reviewing all of the major handlers of stimulants in the State. On September 24, 1986, DEA Investigators conducted an accountability audit of the Schedule II stimulants at Respondent pharmacy for the period between May 1, 1985 and September 24, 1986. The audit revealed a shortage of 18,603 dosage units of Preludin. Further, review of the Schedule II prescription files during the audit period revealed that the pharmacy had filled 4,964 prescriptions, of which 3,801 were for stimulants. Of these, 3,233 prescriptions were for Preludin, a highly abused Schedule II controlled substance.

DEA Investigators reviewed the prescriptions for Preludin and found that 1,935 of the prescriptions had been issued by Dr. Bevilacqua, a physician who was under investigation by DEA at the time of the audit. On some days the pharmacy filled between 10 and 30 Preludin prescriptions issued by Dr. Bevilacqua. For example, the pharmacy filled 15 Preludin prescriptions issued by Dr. Bevilacqua on July 1, 1986; 12 prescriptions were filled on July 3, 1986; 12 prescriptions on July 18, 1986; and 25 prescriptions on July 29, 1986. At the administrative hearing, a DEA Investigator testified that according to court documentation and reports filed in connection with Dr. Bevilacqua's criminal case, his office opened at 4:30 or 5:30 a.m. with mobs of people waiting to enter. Individuals were paid by others to obtain prescriptions from Dr. Bevilacqua who provided everyone with a prescription for Preludin and also provided many with a prescription for Talwin. Individuals signed a list, sometimes using as many as ten different names in one day, and received a prescription in each of those names. In December 1987, after entering a guilty plea, Dr. Bevilacqua was convicted of illegally dispensing controlled substances. Mr. Bertolino testified that Dr. Bevilacqua's office was about ten blocks away from his pharmacy, that he had not seen Dr. Bevilacqua in thirty years, and that he was unaware of the true nature of Dr. Bevilacqua's practice until he read a newspaper account of Dr. Bevilacqua's having pled guilty to drug-related crimes. Mr. Bertolino also testified that except for the first or second prescription he received from Dr. Bevilacqua, he did not call to verify prescriptions. He explained that he knew Dr. Bevilacqua ran a diet clinic; therefore, Preludin prescriptions were not surprising.

With respect to the shortage of 18,603 dosage units of Preludin, Mr. Bertolino claimed that in January 1987, his son found a box in the pharmacy which contained bottles of Preludin that apparently had not been shown to the DEA Investigators at the time they conducted their audit. Although he did not actually count the number of bottles found, Mr. Bertolino assumed that the box contained either 180 or 190 bottles. To further substantiate his claim that the pharmacy was not short 18,603 Preludin tablets, Mr. Bertolino conducted an audit for the period between September 24, 1986 and July 17, 1987, which showed that the pharmacy dispensed approximately 107,400 dosage units of Preludin. Taking into account the inventory and purchase figures provided in the audit, the pharmacy could not have dispensed 107,400 dosage units of Preludin unless it had approximately 18,000 Preludin tablets in the pharmacy the day DEA conducted its audit.

DEA Investigators reviewed the Preludin prescriptions filled by the pharmacy between September 24, 1986, and July 17, 1987, the period covered by Mr. Bertolino's audit. Two thousand three hundred seventy-eight prescriptions were filled, totalling 107,407 dosage units of Preludin tablets. Of these, a Dr. Williams issued 1,179 prescriptions, accounting for 70,260 dosage units of the total Preludin dispensed. One thousand one hundred sixty-three prescriptions issued by Dr. Williams were for sixty dosage units of Preludin. For at least forty individuals, Dr. Williams issued these prescriptions more often than every sixty days, although the Physicians' Desk Reference (PDR) lists the maximum recommended dosage as one tablet per day.

Further, the Administrator finds that an analysis of the 2,378 prescriptions filled at the pharmacy between September 24, 1986 and July 17, 1987,

revealed that Respondent filled prescriptions for Preludin for many individuals regularly over a period of months notwithstanding Preludin's labelling which warns that the product should not be taken for more than a few weeks. For example, Respondent dispensed 270 Preludin tablets to one individual in less than seven months pursuant to prescriptions issued by three different doctors; another individual obtained 210 dosage units of Preludin over an eight-and-a-half month period pursuant to prescriptions issued by four different doctors; another individual received 360 dosage units in a nine-month period pursuant to prescriptions issued by four different doctors; another individual obtained 390 dosage units of Preludin during a ten-month period.

The record reveals that other individuals also presented prescriptions for Preludin 75 mg. from more than one physician thereby obtaining more than the recommended 30 dosage units per month. For example, one individual had a prescription for thirty dosage units of Preludin from Dr. Karlin filled on September 25, 1986, and another prescription for the same amount from Dr. Bevilacqua filled the next day. Another individual had a prescription for sixty dosage units from Dr. Willard filled on October 1, 1986, a prescription for fifty dosage units from Dr. Johnson on November 3, 1986, and prescriptions from Dr. Willard again on December 3, 1986, January 5, 1987, March 2, 1987, April 15, 1987, and June 9, 1987, each time for sixty dosage units of Preludin.

Concerning the procedures and policies for filling a prescription at the pharmacy, Mr. Bertolino testified that he examines the prescription to see whether it has been altered, copied or changed and then checks the identification of the individual who presented the prescription. If he has no prior knowledge of wrongdoing by the physician, he will fill the prescription. If he detects something suspicious, he will call the doctor to verify that he issued it.

The administrative law judge recommended that Respondent's DEA Certificate of Registration be revoked. The Administrator adopts the opinion and recommended ruling of the administrative law judge.

In determining whether a registrant's continued registration is inconsistent with the public interest, the Administrator considers the following factors listed in 21 U.S.C. 823(f); and referred to in 21 U.S.C. 824(a)(4):

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

The Administrator is not required to make findings with respect to all of the factors listed above. The Administrator has the discretion to give each factor the weight he deems appropriate, depending upon the facts and circumstances in each case. See *David E. Trawick, D.D.S.*, Docket No. 86-69, 53 FR 5326 (1988); *England Pharmacy*, 52 FR 1674 (1987).

In this case, the second, fourth and fifth factors are relevant. The Administrator finds that the pattern of dispensing in this case is conduct which threatens the public health and safety. Respondent knew, or should have known, that the Preludin he dispensed was being obtained for other than legitimate medical purposes. The sheer quantity and frequency of prescriptions for Preludin, a highly abused Schedule II controlled substance, issued by Drs. Bevilacqua and Williams should have prompted Mr. Bertolino to question their legitimacy and ultimately decide not to fill them. When controlled substances are being dispensed pursuant to a prescription, the law and regulations place a corresponding responsibility on both the prescribing practitioner and the dispensing pharmacist. The applicable regulation, 21 CFR 1306.04 (a) provides, in part, that:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The language in 21 CFR 1306.04 and relevant caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons. See, *United States* v. *Hayes* 595 F.2d 258 (5th Cir. 1979) cert. denied, 444 U.S. 866 (1979); *United States* v. *Henry*, 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds). A pharmacist must exercise professional judgment when filling a prescription issued by a physician. In this case, Respondent failed to exercise any professional judgment before filling thousands of prescriptions for Preludin, a highly abused controlled substance, issued by Dr. Bevilacqua and Dr. Williams.

The statutory scheme plainly requires that pharmacists use common sense and professional judgment. When their suspicions are aroused as reasonable professionals, either by ambiguities in the prescriptions or, as in this case, the sheer volume of controlled substances prescribed by a few physicians or obtained by some patients from several physicians, pharmacists are called upon to obey the law and refuse to dispense. To fail to do so is either gross incompetence, gross negligence or criminal behavior. Respondent argues that he neither knew, nor had reason to know, that these physicians were issuing prescriptions for other than legitimate medical purposes. The Administrator rejects this argument. The sheer number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment, and the very nature of Preludin as a highly-abused drug, are all factors which should have prompted Respondent to question the prescriptions and refuse to fill them. However, according to Mr. Bertolino's testimony, none of these factors play a role in his decision to fill a prescription.

When prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid positive knowledge of the real purpose of the prescription, thereafter filling them with impunity. See *United States* v. *Kershman*, 555 F.2d 198 (8th Cir. 1977); *United States* v. *Hayes*, 595 F.2d 258 (5th Cir. 1979). In this case, Respondent simply closed his eyes to obvious abuse, ignoring the fact that his customers were purchasing far more medication than would be necessary for legitimate medical purposes.

In filling thousands of prescriptions for Preludin, Mr. Bertolino abdicated his responsibility as a pharmacist and as a registrant. A profession is a vocation or occupation requiring special and advanced education and skill. The practice of pharmacy, like the practice of medicine, is a profession. Society entrusts to persons in these professions the responsibility for control over a

force which, when properly used, has great benefit for mankind, but when abused is a force for evil and human destruction. It follows that society cannot tolerate within these professions the presence of individuals who abdicate their professional responsibility and permit themselves to be used as a conduit by which controlled substances reach the illicit market and become that force of evil. See, *Vermont & 110th Medical Arts Pharmacy, et al.* v. *Board of Pharmacy*, 125 Cal. App. 3d 19 (1981). When such abdication of responsibility involves a DEA registrant, the public interest clearly requires that the registration be revoked. The registration of Ralph J. Betolino Pharmacy is contrary to the public interest and the Administrator concludes that it must be revoked.

In his exceptions to the administrative law judge's opinion and recommended ruling, Respondent raised ten points in urging that he be permitted to retain his registration. First, he argues that many of the scheduling orders and evidentiary rulings made by the Administrative law judge were unfair and incorrect. After careful review of the chronology of event, the Administrator finds no merit in Respondent's arguments. He had ample opportunity to prepare his defense and the administrative law judge's evidentiary rulings relating to timeliness and exclusion of proffered documents were proper and consistent with the Agency's established disclosure procedures and rules. Second, Respondent argues that the administrative law judge erroneously permitted the Government to refer to the Physicians' Desk Reference in Government Exhibit No. 4. The Administrator finds that the administrative law judge's ruling was correct for the reasons stated in her opinion and recommended ruling. Further, after careful review of the record in this case, the Administrator finds no merit in any of the arguments raised by Respondent in his exceptions to the adminstrative law judge's opinion and recommended ruling.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that DEA Certificate of Registration AB2343503, previously issued to Ralph J. Bertolino Pharmacy be, and hereby is, revoked. The Administrator further orders that any pending applications for renewal of said registration be, and they hereby are, denied.

This order is effective March 12, 1990.

Dated: February 5, 1990.

John C. Lawn,

Administrator.

[FR Doc. 90-3043 Filed 2-8-90; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Application

Pursuant to section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on August 28, 1989, Western FHER Laboratories, Inc., Carretera 132, KM.25.3, Ponce, PR 00732, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the Schedule II controlled substance phenmetrazine and its salts (1631).

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 and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than March 12, 1990.

Dated: January 30, 1990.

Gene R. Haislip,

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

[FR Doc. 90-3049 Filed 2-8-90; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

Background

The Department of Labor, in carrying out its responsibilities under the Paperwork Reduction Act (44 U.S.C. chapter 35), considers comments on the reporting and recordkeeping requirements that will affect the public.

List of Recordkeeping Reporting/ Requirements Under Review

As necessary, the Department of Labor will publish a list of the Agency recordkeeping/reporting requirements under review by the Office of Management and Budget (OMB) since the last list was published. The list will have all entries grouped into new collections, revisions, extensions, or reinstatements. The Departmental Clearance Officer will, upon request, be able to advise members of the public of the nature of the particular submission they are interested in.

Each entry may contain the following information:

The Agency of the Department issuing this recordkeeping/reporting requirement.

The title of the recordkeeping/ reporting requirement.

The OMB and Agency identification numbers, if applicable.

How often the recordkeeping/ reporting requirement is needed.

Who will be required to or asked to report or keep records.

Whether small businesses or organizations are affected.

An estimate of the total number of hours needed to comply with the recordkeeping/reporting requirements and the average hours per respondent.

The number of forms in the request for approval, if applicable.

An abstract describing the need for and uses of the intormation collection.

Comments and Questions

Copies of the recordkeeping/reporting requirements may be obtained by calling the Departmental Clearance Officer, Paul E. Larson, telephone (202) 523-6331. Comments and questions about the items on this list should be directed to Mr. Larson, Office of Information Management, U.S. Department of Labor, 200 Constitution Avenue, NW., room N-1301, Washington, DC 20210. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ ESA/ETA/OLMS/MSHA/OSHA/ PWBA/VETS), Office of Management and Budget, room 3208, Washington, DC 20503 (Telephone (202) 395-6880).

Any member of the public who wants to comment on a recordkeeping/ reporting requirement which has been submitted to OMB should advise Mr. Larson of this intent at the earliest possible date.

Extension

Occupational Safety and Health Administration.

Acrylonitrile Standard.

1218-0126.

On occasion.