Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, Washington Center, 1331 G Street, NW, Washington, DC 20530.

Dated: December 21, 1999.

Brenda E. Dyer,

Department Deputy Clearance Officer, Department of Justice.

[FR Doc. 99–33549 Filed 12–27–99; 8:45 am]

BILLING CODE 4410–AT–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on November 4, 1999, Celgene Corporation, 7 Powder Horn Drive, Warren, New Jersey 07059, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of methylphenidate (1724) a basic class of controlled substance listed in Schedule II.

The firm plans to manufacture methylphenidate for product research and development.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the proposed registration.

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 28, 2000.

Dated: December 16, 1999.

John H. King,

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

[FR Doc. 99–33648 Filed 12–27–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 6, 1999, and published in the **Federal Register** on August 20, 1999, (64 FR 45564), Guilford Pharmaceuticals, Inc., 6611 Tributary Street, Baltimore, Maryland 21224, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of cocaine (9041), a basic class of controlled substance listed in Schedule II

The firm plans to manufacture methyl-3-beta-(4-trimethylstannylphenyl)-tropane-2-carboxylate as a final intermediate for the production of dopascan injection.

DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Guilford Pharmaceuticals to manufacture the listed controlled substance is consistent with the public interest at this time. DEA has investigated the firm 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 conpany'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 class of controlled substance listed above is granted.

Dated: December 16, 1999.

John H. King,

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

[FR Doc. 99–33645 Filed 12–27–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96–10]

Wesley G. Harline, M.D.; Continuation of Registration With Restrictions

On October 27, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Wesley Harline, M.D. (Respondent) of Ogden, Utah, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AH1650248 and deny any pending applications for renewal of such registration as a practitioner pursuant to 21 U.S.C. 823(f) and 824(a)(4), for reason that his continued registration would be inconsistent with the public interest.

By letter dated December 14, 1995, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Salt Lake City, Utah on April 1 through 3 and May 6 through 8, 1997, and by telephone in Salt Lake City and Arlington, Virginia, on August 18 through 21, 1997, before Administrative Law Judge Mary Ellen Bittner. At the hearing both parties called witnesses to testify and introduced documentary evidence. After the hearing both parties submitted proposed findings of fact, conclusions of law and argument.

In this brief, Respondent's counsel included findings based upon evidence that was not introduced at the hearing. On January 5, 1998, the Government filed a Motion to Strike Post Record Evidence from Respondent's Proposed Findings of Fact, Conclusions of Law and Argument. On January 21, 1998, Respondent filed his Opposition to Government's Motion to Strike Post Record Evidence, and in the alternative, Motion to Reopen the Record.

On April 2, 1999, Judge Bittner issued her Opinion and Recommended Ruling Findings of Fact, Conclusions of Law and Decision (Opinion), granting the Government's motion to strike the additional evidence, denying Respondent's motion to reopen the record, and recommending that Respondent's DEA Certificate of Registration be revoked and any pending applications be denied. On June 14, 1999, Respondent filed exceptions to Judge Bittner's Opinion and on August 2, 1999, the Government filed its response to Respondent's exceptions. Thereafter, on August 10, 1999, Judge Bittner transmitted the record of these proceedings to the Deputy Administrator.

While this matter was pending with the Deputy Administrator, Respondent submitted a letter dated November 4, 1999, responding to the Government's response to his exceptions and formally moving that the record be reopened to allow additional evidence to be considered. As will be discussed more fully below, the Acting Deputy Administrator denies Respondent's motion to reopen the record and has not considered Respondent's letter dated November 4, 1999, in rendering his decision in this matter.

The Acting Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Acting Deputy Administrator adopts, except as

specifically noted below, the findings of fact set forth in Judge Bittner's Opinion, but does not adopt Judge Bittner's recommended conclusions of law and decision.

The Acting Deputy Administrator finds that Respondents graduated from medical school in 1945. In or about 1953, Respondent joined a general surgery practice in Ogden, Utah. He has been a licensed physician in Utah since 1953 and has held state and Federal authorizations to handle controlled substances since approximately the time he obtained his medical license. According to Respondent, sometime in the 1980s, he virtually terminated his general surgery practice to concentrate on cosmetic surgery. Respondent testified that he considered weight control to be a part of cosmetic surgery, and as of 1997, he saw 15 to 20 weight control patients every weekday and a few weight control patients on Saturdays.

Primarily at issue in this proceeding is whether Respondent properly prescribed controlled substances to his weight control patients. Therefore, provisions of Utah law relating to this issue were placed into evidence. As of 1987 [1], the Utah Administrative Code (Administrative Code) authorized the Utah Division of Occupational and Professional Licensing (DOPL) to revoke a State license to handle controlled substances if the holder ''[p]rescribes or administers any controlled substance for weight control for more than 30 days in any 12 twelve-month period.'' Utah Admin. Code R153–37–8 (1987–1988). The Administrative Code also required that ''each prescription for a controlled substance and the number of refills authorized shall be documented in the patient records by the prescribing practitioner.'' Utah Admin. Code R153–37–10.D (1987–1988).

The 1989 Administrative Code generally provided that:

> Prescribing practitioners shall keep accurate records reflecting the examination, evaluation and treatment of all patients. Patient medical records shall accurately reflect the prescription or administration of controlled substances in the treatment of the patient, the purpose for which the controlled substances is utilized and information upon which the diagnosis is based.

Utah Admin. Code R153–37–.A (1989). Further, Utah Admin. Code R153–37–10.H (1989), provided that Schedule II controlled substances could not be prescribed, dispensed or administered for weight reduction or control. In addition, section 10.J essentially provided that Schedule III and IV controlled substances could only be used for weight reduction in the treatment of obesity as an adjunct, in accordance with Food and Drug Administration approved labeling for the product, and in a regimen of caloric restriction provided that among other things the prescribing practitioner determines that the patient has made good faith efforts to lose weight in a structured treatment program and the program was ineffective; obtains a thorough history; performs a thorough physical examination; and rules out any contraindications to the use of controlled substances. This section precluded the prescribing of Schedule III and IV controlled substances for weight reduction for a period longer than 12 weeks in any one year period. Also pursuant to this section, a practitioner was required to discontinue prescribing controlled substances if the patient failed to lose weight while under treatment for a period of 28 days as determined by weighing of the patient at least every fourteenth day.

In 1991, the provision was reworded slightly but essentially was substantively unchanged, and remained so until January 29, 1996. As of that date, Utah Admin. Code R156–37–604 (1996) provided that Schedule II and III controlled substances shall not be prescribed, dispensed, or administered for purposes of weight reduction or control. Further, Schedule IV controlled substances can only be used in the treatment of excessive weight when certain conditions are met. However, this provision no longer imposed the 12 week limitation on the use of Schedule IV controlled substances.

On June 5, 1992, the DOPL issued an emergency under restricting Respondent's authority to perform certain types of surgery and ordering him to cease providing overnight patient care at his facility. On September 29, 1993, a Third Amended Petition was filed in that proceeding alleging, among other things, that Respondent prescribed a Schedule III anorectic controlled substance beyond the period of time permitted by Utah regulation to at least 13 patients and that the prescriptions did not bear the full names and addresses of the patients and the dates issued as required by law.

On December 10, 1996, Respondent executed a Stipulation and Order in which he denied all of the allegations of the Third Amended Petition but agreed to various terms and conditions. Specifically, the Stipulation and Order suspended Respondent's medical license for three months, but stayed enforcement of the suspension and placed his license on a five-year probation subject to various conditions including that he provide adequate means to permit patients to exercise informed consent with respect to medical and surgical procedures, anesthesia, and medications to be administered or dispensed; meet with the Physicians' Licensing Board (Board) quarterly for five years; allow a qualified physician to review records of 1.4 percent of his patients; and maintain prescription records in accordance with State and Federal law and make his prescription records available for inspection by the board and the DOPL upon request.

In the latter half of 1995, DEA conducted a pharmacy survey to determine whether Respondent was complying the various regulatory requirements. The survey revealed that Respondent had written prescriptions for anorectic controlled substances for more than 12 weeks in a year in violation of state law. The survey further revealed seven prescriptions that Respondent issued between 1993 and 1995 and 202 prescriptions that he issued between 1990 and 1992 that did not bear the patient's full name and/or date of issuance.

Respondent testified that he had written incomplete prescriptions, but that in discussions with other physicians he had learned that such prescriptions ''are a quite frequent occurrence.'' According to Respondent, he was told by a DOPL investigator that no more than 50% of prescriptions for Schedule II, IV and V controlled substances are properly filled out.

On May 11, 1995, DOPL subpoenaed records for 43 of Respondents's patients. At issue in this proceeding is whether Respondent properly prescribed controlled substances to these patients for weight control. As a result, there was evidence presented by both the Government and Respondent regarding when an individual is considered obese or overweight, when the use of controlled substances is appropriate for weight control, and when such treatment is deemed effective. The Government offered the testimony of a physician who mainly treats chronic pain patients, but who was qualified as an expert in the legitimate use of anorectic controlled substances. Respondent testified on his own behalf and also offered the testimony of a physician whose practice prior to 1991 consisted of some weight management patients and since 1991 was solely weight management patients. Both parties offered extensive documentary evidence.

[1] The Government did not provide any evidence of the statutory provisions relating to weight control in existence prior to 1987.

Evidence was presented that different methods are used to determine when a patient is considered obese or overweight. These include comparing the patient's height and weight to charts published by insurance companies, and calculating the individual's body mass index (BMI), which is the person's weight in kilograms divided by the square of his/her height in meters. The Government's expert as well as most of the documentary evidence regarding this issue cite BMI as the best general guideline. Judge Bittner went into great detail, which will not be repeated here, summarizing the various opinions in evidence regarding at what BMI an individual is considered obese or overweight. After reviewing all of the evidence, the Acting Deputy Administrator finds that there seems to be disagreement within the medical community as to when an individual is considered obese or overweight using BMI as a guideline.

Respondent testified that his standard practice for weight control patients during the time period at issue was to use the life insurance tables, and that he was not aware of BMI as a criterion until the 1990s. He further testified that although BMI is ''helpful'' in determining whether or not to prescribe weight control medication, he found it cumbersome to use.

Judge Bittner concluded that:

> Based on my review of all the foregoing, and recognizing that there is some disagreement among the experts, I find that for purposes of this proceeding the [National Institute of Health's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)] definitions are the most appropriate standards. I therefore find that a person aged thirty-five or older is obese if he or she has a BMI of 27 [kilograms/meters squared] or more, that person age thirty-four or younger should be considered obese if he or she has a BMI of 25 [kilograms/meters squared] or more, and that a BMI greater than 30 [kilograms/meters squared] indicates moderate to severe obesity.

The Acting Deputy Administrator disagrees with Judge Bittner that the NIDDK definitions are the most appropriate standards. The Acting Deputy Administrator finds that given the disagreement within the medical community, he is not comfortable finding that one standard is more appropriate than another. In fact the NIDDK standard that Judge Bittner cites also noted that while BMI ''is the measurement of choice for many physicians and researchers studying obesity,'' it

> poses some of the same problems as the height-for-weight tables. Doctors don't agree on the cutoff points for ''healthy'' versus ''unhealthy'' BMI ranges. BMI does not provide information on a person's percentage of body fat. However, like the height-for weight table, BMI is a useful general guideline.

Understanding Adult Obesity, NIH Publication No. 94–3680, November 1993 <http://www.niddk.nih.gov/Aobesity/adultobe.htm>.

Therefore, the Acting Deputy Administrator is reluctant to set an objective standard to determine when an individual is considered obese or overweight which might not necessarily be appropriate for each patient. Rather it appears that there are a number of different criteria that may be considered by a physician in determining whether an individual patient is obese or overweight.

Next, Judge Bittner addressed when it is appropriate to use controlled substances in a weight loss program. A consensus of the documentary evidence, as well as the testimony of both Respondent and the Government's expert, indicate that obesity is a chronic condition, and as such, using medication to treat it only for a short time is not effective. However, by virtue of the fact that the drugs at issue are controlled substances, it has already been determined that these drugs have some potential for abuse and that abuse would lead to some level of physical or psychological dependence.

The Physicians' Desk Reference (PDR) advises that these drugs should only be used for a few weeks. However, DEA has previously held that the PDR is not binding on a physician. See Paul W. Saxton, D.O., 64 FR 25, 073 (1999); Margaret E. Sarver, M.D., 61 FR 57, 896 (1996). Even the Government's expert testified that research has found that the Food and Drug Administration recommendations on which the PDR is based may be too restrictive, at least for some Schedule IV substances. The Government's expert further testified that the risks associated with the controlled substances at issue here are low and that the medications are reasonably safe drugs, but that they do have side effects and there is some potential for abuse, although low for Schedule IV substances. The Government's expert testified that the potential benefit of using controlled substances must be balanced against the potential risk.

Judge Bittner went into great detail, which will not be reiterated here, regarding the documentary evidence regarding tolerance and the abuse potential associated with anorectic controlled substances and as to their efficacy. After reviewing all of this evidence, the Acting Deputy Administrator concludes that there have been few if any meaningful studies on the long-term use of anorectic controlled substances in the treatment of weight control.

However, the Acting Deputy Administrator finds it noteworthy that in the prologue to the Anorectic Usage Guidelines adopted by the American Society of Bariatric Physicians on November 10, 1990 (1990 ASBP Prologue) it was reported that the reported incidence of serious side effects of Schedule III and IV anorectics ''is low indeed.'' The 1990 ASBP Prologue also stated, among other things, that short and long term studies have not documented concerns about the abuse potential of anorectics, and that a significant number of bariatric physicians reported that they maintained patients on anorectics for long periods of time without significant ill effects. The 1990 ASBP Guidelines stated that Schedule III and IV anorectics ''can often be useful in helping patients to lose weight and to maintain a reduced weight,'' and that these medications ''by definition have a low level of risk and little potential for addiction or psychologic dependence when carefully used by a physician in a properly supervised medical practice.''

The Acting Deputy Administrator also finds it significant that in a 1996 article,[2] the National Task Force on the Prevention and Treatment of Obesity (National Task Force) advised that obesity is likely to require continued treatment, and that therefore drug treatments for only weeks or months is generally not warranted. The National Task Force warned that drug treatment might need to continue for years, even for the patient's lifetime, but that there were few published studies in which patients received these drugs for more than a year. Consequently, the Acting Deputy Administrator is reluctant to find that long-term use of anorectic controlled substances is inappropriate.

Judge Bittner next addressed the criteria for an appropriate weight loss program utilizing controlled substances. The Government's expert and the documentary evidence suggest that controlled substances should only be used as part of an overall program including dietary modification, behavioral instruction and exercise. The Government's expert emphasized that the key determinant of a weight loss program's efficacy is whether the weight

[2] National Task Force on the Prevention and Treatment of Obesity, Long-term Pharmacotherapy in the Management of Obesity, 276 JAMA 1907 (1996).

loss improves the patient's health. It was the opinion of the Government's expert that it is not appropriate to use controlled substances for weight loss in order to enhance a patient's self-image or for prophylactic use, for instance if other members of a patient's family are overweight. According to the Government's expert it is not appropriate to prescribe controlled substances for cosmetic purposes.

Respondent testified that in determining whether to prescribe medications for weight control he considered the patient's feelings about him or herself, whether he or she wanted to lose weight, how much the patient wanted to lose, and whether it was feasible for the patient to do so.

The Government's expert testified that a weight loss of at least 10% is considered a good sustained weight loss. Other evidence in the record indicates that some believe that a weight loss as low as 5% is considered good. The Government's expert testified that once a 10% weight loss has been achieved, that does not necessarily mean that controlled substances should be discontinued because the medication helps prevent regaining weight loss. But the expert further testified that there needs to be an ongoing review process to assess the efficacy of the use of controlled substances.

Judge Bittner went into great detail summarizing the documentary evidence relating to the criteria for determining when controlled substances should be utilized in a weight control program. After considering all of the evidence the Acting Deputy Administrator concludes that there appears to be a difference of opinion within the medical community as to when it is appropriate to use controlled substances in a weight management program and when such use is considered effective.

The Acting Deputy Administrator finds it significant that the 1990 ASBP Guidelines specify that the guidelines,

> provide suggestions regarding the use of the anorectics but they are not intended to and indeed cannot, replace the individual judgment of the treating bariatrician which remains and must remain paramount. Thus, the bariatrician must not rely on these guidelines, or on any other guidelines to provide an infallible blueprint for patient treatment. It is not the intent of these guidelines to limit the bariatricians' right to adjust the therapy based on the patient's condition, medical problems or therapeutic response.

The Government's expert testified that this statement should be interpreted in the context of a clear-cut treatment program with established goals.

Judge Bittner concluded that

> [i]n light of my findings above as to when a person should be considered obese, I further find that anorectic controlled substances should not be used in the treatment of a patient unless the individual is thirty-five or more years of age and has a BMI of at least 27 [kilograms/meters squared], or, if younger than thirty-five years of age, has a BMI of 25 [kilograms/meters squared] or more. I especially note that the evidence establishes that prescribing controlled substances to a patient for cosmetic purposes is not within the scope of legitimate medical practice.
>
> * * * Based on my review of the record and for purposes of this proceeding, I find that it is appropriate to continue prescribing anorectic controlled substances to those patients who initially are candidates for such treatment only if (a) the patient achieves a loss of five percent of body weight or a reduction in BMI by one or more units and maintains that loss for at least one year, or (b) if the patient achieves a significant clinical response as defined in the 1990 ASBP Guidelines, *i.e.,* (1) a loss of at least twelve pounds over the initial twelve weeks, and (2) a loss of at least four pounds for each additional four weeks of treatment, providing that if the patient has lost at least ten percent of his or her initial body weight, he or she may be considered to have reached [90% Target Weight] and may appropriately continue to be prescribed anorectics if needed. If the patient gains weight and exceeds that benchmark, the physician should cease prescribing the medications unless the patient again achieves the [90% Target Weight] benchmark in a period of time equaling one week for each pound above the benchmark. (Footnotes omitted).

The Acting Deputy Administrator disagrees with these findings. There appears to be differing opinions within the medical community as to when it is appropriate to use controlled substances in weight management treatment and when such use is considered effective. As a result, the Acting Deputy Administrator is not comfortable setting objective standards which might not necessarily be appropriate for each individual patient.

As to the 42 patients at issue in this proceeding, Judge Bittner went into great detail in her Opinion regarding their history of treatment with Respondent. She discussed the patient charts and patient summaries in evidence, the assessment of the Government's expert of each patient, Respondent's testimony regarding each patient, and the patient interviews conducted by DEA and/or the patients' testimony. Since the Acting Deputy Administrator is adopting Judge Bittner's findings of fact except as specifically noted, there is no need for him to reiterate them. It should be noted that based upon the Acting Deputy Administrator's rejection of certain of Judge Bittner's findings as noted above, the Acting Deputy Administrator does not adopt any of Judge Bittner's findings regarding specific patients that use her objective standard to conclude the treatment with controlled substances was inappropriate or to assess whether or not treatment was successful.

The Acting Deputy Administrator makes the following general findings regarding Respondent's treatment of the patients at issue. These patients were all being treated by Respondent for weight loss or management. There is no evidence that anorectic controlled substances were prescribed for other purposes, or that controlled substances received pursuant to Respondent's prescriptions were sold or in any other way diverted from the patients' use.

On the initial visit, the patient would be weighed, his/her height would be measured and blood pressure taken. A family/medical history would be taken and Respondent would perform a physical examination. Respondent would discuss goals and a target weight with the patient, give the patient a generalized diet, generally discuss exercise, lifestyle changes, and possible side effects of the controlled substances, and ask whether the patient had previously attempted to lose weight and by what methods.

Thereafter, Respondent would see the patient no more than once a month. In fact, several patients testified that they had tried to obtain their prescriptions earlier because they were going on vacation, but their requests were refused. At each visit the patient would be weighed and his/her blood pressure taken. The patient would always be seen by Respondent before any controlled substances would be prescribed. Respondent would admonish the patient if he/she were not losing weight. If the patient was not losing weight, Respondent would very rarely change the diet he had provided the patient because according to Respondent, more likely than not the patient was not following the diet. Respondent would remind the patient on follow-up visits of the importance of following the diet.

Respondent testified that he used the insurance company height and weight tables to determine whether to use controlled substances in the treatment of a patient. However, he also testified that he is now stricter in his approach to weight control treatment.

Respondent's office manager testified that although a patient's blood pressure was taken at each visit, the result was not always noted in the patient's chart unless it was abnormal. Respondent testified that he might not always note the responses to the medical/family history questions or the results of the

physical examination in the patient's chart if the responses and/or findings were normal.

For the most part, the charts for the patients at issue here not do indicate the patient's target weight, medical history, or results of physical examinations, nor do the charts indicate whether the patient previously saw another physician for weight control or was ever enrolled in a formal weight control program. Also, for the most part, there is no indication in the charts that Respondent gave the patient diet or exercise information on an initial or subsequent visit, or that Respondent subsequently discussed these subjects with the patient or modified the recommended diet and exercise regimens. Also there were several instances where controlled substances were prescribed by Respondent but not noted in the patient charts. In addition, a number of the patients were prescribed benzodiazepines for extended periods of time with no reason for these prescriptions noted in the charts.

The Government's expert testified that Respondent's patient records did not comply with Utah requirements regarding patient histories and physical examinations, and characterized Respondent's records as ''grossly deficient * * * in terms of the evaluation of the patients.'' According to the Government's expert, as far as the patient records show, ''the patients came in, were weighed, were given a prescription and left * * * That's all you can tell from the records. This isn't saying other things weren't done, but certainly they weren't documented if they were.''

Respondent testified that the medical records in evidence as Government exhibits were incomplete, and included only his handwritten notes, not all of the information in the patient charts, and that these notes were the only portions of the charts that DEA investigators asked his staff to copy. However as Judge Bittner pointed out, Respondent did not object when the Government offered the charts into evidence, did not request that the Government be required to introduce other documents at that time, and did not offer the complete charts as his own exhibits. Regarding the benzodiazepine prescriptions, while the reasons for the prescriptions were not noted in the charts, Respondent and the patients who testified were able to give explanations for the prescriptions. Nonetheless, Respondent admitted at the hearing that his patient records were not as good as they could have been.

Respondent also admitted that with respect to all 42 patients at issue in this proceeding, he violated Utah law in existence at the time that limited the prescribing of Schedule III and IV anorectic controlled substances to no more than 12 weeks in a one-year period (12-week rule). Respondent testified that he did not agree with Utah's pre-1996 restriction because a weight control program for 12 weeks is not feasible and that the rule was not in the mainstream of medicine. According to Respondent, ''I thought I was still in the mainstream of medicine, because most of my colleagues were violating the 12-week rule and certainly all of the drugstores were.'' Respondent asserted that ''that doesn't make me any less guilty, but it explains why I did it.'' Respondent testified that he should not have disobeyed the law but he felt that it was in the best interest of his patients. He further testified that his patients have been inconvenienced and embarrassed by their involvement in these proceedings, and that his health has suffered and he has been financially burdened due to his violation of the law.

In general, the Government's expert opined that it did not appear that Respondent monitored the patients' treatment; that the patient interviews failed to show the Respondent used any behavior therapy; that many of Respondent's patients did not qualify as candidates for treatment with anorectic controlled substances ''under any definition,'' and that it did not appear that Respondent placed his patients on structured diet and exercise programs. The Government's expert testified that the lack of documentation in the patient charts raised questions about the quality of care that Respondent provided these patients.

For the most part, the Government's expert concluded that Respondent's treatment of the patients at issue with controlled substances was not appropriate. Respondent admitted that his treatment of 10 of the patients was a failure. However, even the Government's expert conceded that Respondent's treatment of several of the patients was successful and he characterized Respondent's treatment of several others as minimally effective.

Respondent's treatment of one patient is of particular concern. From January 1993 to May 1995, the patient was prescribed Nardil, a non-controlled antidepressant, as well as anorectic controlled substances. The Government's expert characterized Nardil as a ''fairly dangerous medication,'' that is typically prescribed by psychiatrists. According to the Government's expert, even many psychiatrists are reluctant to prescribe Nardil because it interacts with a number of other drugs, particularly anorectics, and some foods which can lead to life threatening side effects. At the hearing in this matter, Respondent conceded that he made a mistake and should not have prescribed Nardil for this patient.

At the hearing in this matter, Respondent testified that he did not know when he became aware of the 12-week rule. He further testified that he was not aware of the change in Utah law effective January 16, 1996, which prohibited the prescribing of Schedule III controlled substances for weight control and which eliminated the 12-week rule for Schedule IV controlled substances, until he was personally advised of this change by a DOPL inspector in February 1996. A pharmacy survey revealed that Respondent had issued 16 prescriptions for Schedule III anorectics after the effective date of the law prohibiting such prescribing but before he was advised of the change in the law by the DOPL inspector.

There was also an allegation raised at the hearing that Respondent authorized a pharmacy to change a prescription that he had written on March 12, 1996 for a Schedule IV controlled substance to a Schedule III controlled substance. A DOPL investigator testified that a pharmacy technician indicated that the patient requested the change and the pharmacy technician had gotten approval from someone at Respondent's office. Respondent testified that the individual at his office did not recall giving the pharmacy technician authorization to change the prescription. Respondent further testified that ''I'm not stupid. I have been notified months previous that this was no longer a drug that we prescribed,'' and that he would not have authorized such a change.

Evidence was presented by Respondent regarding his practice as of the date of the hearing. Respondent testified that his patient charts have been ''up to speed'' from the time he entered into the agreement with the state to undergo peer review. Also as of August 1997, he follows procedures specified in a document that was prepared with the assistance of counsel which includes a checklist for the physician on the initial consult, a medical history form, an informed consent form, and a follow-up consultation questionnaire. These forms all remain as part of each patient's permanent record. Respondent's office manager testified that weight control patients are now given a handbook

which includes information on diet, exercise, and medication. Respondent testified that he is now complying with all State, Federal and local laws pertaining to controlled substances and would never violate a regulation in the future.

In this brief filed after the conclusion of the hearing, Respondent's counsel sought to introduce and rely upon evidence not admitted at the hearing. Respondent's counsel attached and discussed in his brief a letter dated October 2, 1997, from a physician who stated that he had conducted a random sampling of Respondent's charts for weight control patients. In a motion filed on January 5, 1998, the Government objected to consideration of this information arguing that Respondent did not move to reopen the record to receive additional evidence, and even if he had, the record should not be reopened because Respondent has not demonstrated that the evidence was previously unavailable and is material and relevant. See Robert M. Golden, M.D., 61 FR 24,808 (1996). Further the Government asserted that at most, the letter shows that Respondent is complying with his probationary requirements with the Board, which is presumed, and that the letter raises issues of fact that would require further testimony and documentary evidence in this proceeding. On January 21, 1998, Respondent filed his opposition to the Government's motion in which he moved to reopen the record and argued that the letter meets the standard for reopening the record.

In her opinion, Judge Bittner granted the Government's motion to strike from Respondent's brief the October 2, 1997 letter and references to it. Judge Bittner found that to appropriately evaluate the assertions in the October 2, 1997 letter the record would have to be reopened for additional testimony and documentary evidence. Judge Bittner further found that this is not warranted since, ''the most the letter adds to the record is an indication that Respondent is complying with his probation; [and] as the Government asserts, such compliance is presumed.''

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(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.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. See Henry J. Schwarz, Jr., M.D., 54 FR 16, 422 (1989).

Regarding factor one, Judge Bittner noted that Respondent entered into a Stipulation and Order with the DOPL in December 1996, but no restrictions were imposed on his state authorization to handle controlled substances. Judge Bittner concluded however, that ''inasmuch as State licensure is a necessary but not sufficient condition for DEA registration, this factor is not dispositive.'' In his exceptions to Judge Bittner's opinion, Respondent contended that the state ''is in the best position to judge Respondent's fitness to practice.'' Respondent argued that it is ''unfair and excessively punitive'' for DEA to seek to take action against Respondent above and beyond that taken by the state. The Acting Deputy Administrator notes that the recommendation of the appropriate state licensing authority is but one factor to be considered in determining the public interest. However in this case, the Acting Deputy Administrator does find it significant that Utah did not restrict Respondent's ability to handle controlled substances after reviewing Respondent's treatment of his weight control patients, his documentation in his patient charts, and his failure to include all required information on controlled substance prescriptions.

As to factor two, Judge Bittner found that Respondent prescribed the patients at issue anorectic controlled substances for anywhere from a few months to twenty years, and that the vast majority were prescribed Schedule III controlled substances. Judge Bittner noted that ''[a]lthough Respondent introduced evidence on the long-term use of some Schedule IV medications, the record is devoid of such evidence with respect to Schedule III anorectics.'' Judge Bittner evaluated the treatment of these 42 patients and concluded that

> Respondent's treatment of all forty-two patients whose records are in evidence was inappropriate because he did not provide the comprehensive program required by good medical practice. In addition, twenty-six of the patients were not sufficiently overweight to justify treatment with controlled substances at the outset and eight of these became obese while taking the medications. Of the sixteen patients who may initially have been candidates for treatment with anorectic controlled substances, ten did not achieve a weight loss that met the standard of efficacy stated above.

Judge Bittner also found it significant that Respondent prescribed benzodiazepines to 14 patients for substantial periods of time without documenting the reasons for the prescriptions in the patient charts. As a result, Judge Bittner ''conclude[d] that this factor weighs strongly in favor of a finding that Respondent's continued registration would not be in the public interest.''

The Acting Deputy Administrator finds that it does seem like Respondent issued a large number of prescriptions for anorectic controlled substances to the majority of these patients. However, the Acting Deputy Administrator cannot find that Respondent's prescribing was inappropriate. While the record is devoid of much evidence regarding the long-term use of Schedule III anorectics, the Acting Deputy Administrator is reluctant to find that such prescribing is inappropriate. In evaluating this case, it is apparent that there is a variety of opinions within the medical community as to when a person is considered obese or overweight and when it is appropriate to use controlled substances in the treatment of weight control.

DEA has been faced with an analogous situation when it sought to determine whether physician's prescribing for chronic pain patients was appropriate. In one recent case, the then-Deputy Administrator quoted the Administrative Law Judge who stated that ''DEA is in a difficult position, for it is asked to determine appropriate prescribing practices in a treatment area in which the medical profession is not in accord * * *'' Paul W. Saxton, D.O., 64 FR 25, 073 (1999). DEA has previously held that it is not DEA's role to resolve this disagreement. In William F. Skinner, M.D., 60 FR 62, 887 (1995), the then-Deputy Administrator found that, ''the conflicting expert opinion evidence presented leads to the conclusion that the medical community has not reached a consensus as to the appropriate level of prescribing of

controlled substances in the treatment of chronic pain patients * * *. It remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of the Federal and State law.''

As previously noted, the Acting Deputy Administrator does not agree with Judge Bittner's conclusion that a person is obese or overweight at a set BMI. While it is true that there is evidence in the record that BMI is a good, if not the best, measure of obesity, there are still other guidelines that may be considered. In addition there is conflicting evidence in the record as to when it is appropriate to use controlled substances. Consequently, the Acting Deputy Administrator finds that it is not DEA's role to resolve these differences and set the standard for the medical community. This is not to say that physicians have free reign to prescribe anorectic controlled substances for non-legitimate reasons. But in this case, all of the patients at issue were seeking to control their weight and there is no evidence in the record that the controlled substances were diverted from this purpose.

While one might argue that Respondent did not individualize the treatment for these patients as the evidence suggests is appropriate, Respondent did meet with the patients before prescribing controlled substances and when necessary would discuss diet and exercise with the patients. On some occasions, Respondent would cease treatment when the patient failed to follow Respondent's weight control program. Judge Bittner took issue with the amount of time Respondent spent with the patients saying that it was not sufficient to provide individualized therapy. However, the Acting Deputy Administrator is not in a position to find whether the amount of time spent with the patients was sufficient since no evidence was presented as to what is considered an appropriate amount of time.

As for Respondent's prescribing of benzodiazepines for extended periods of time to some of these patients, it is true that Respondent may not have documented his reasons for these prescriptions in the patient charts. However, at the hearing, Respondent and some of these patients testified as to why these controlled substances were prescribed. The Acting Deputy Administrator concludes that he cannot find that these prescriptions were inappropriate based on the fact that the reasons for the prescriptions were not noted in the patients charts.

The Acting Deputy Administrator finds that Respondent's prescribing of Nardil along with anorectic controlled substances to one patient was inappropriate. However, this is the only example of Respondent prescribing contraindicated drugs, and Respondent has admitted that he was wrong in so doing.

Regarding factor three, there is no evidence that Respondent has been convicted of any criminal charges under State or Federal laws relating to the manufacture, distribution, or dispensing of controlled substances.

As to factor four, Respondent's compliance with applicable laws, Respondent has admitted that he violated Utah law with respect to the 42 patients at issue in this proceeding by prescribing anorectic controlled substances to them for more than 12 weeks in a one year period and by failing to properly document his treatment of these patients in their charts. The Acting Deputy Administrator does not find that Respondent violated 21 CFR 1306.04, which states that controlled substances may only be prescribed for a legitimate medical purpose. As discussed above, given the difference of opinion in the medical community, the Acting Deputy Administrator cannot find that Respondent issued controlled substance prescriptions to the patients at issue for no legitimate medical purpose.

As to factor five, Judge Bittner concluded that Respondent did not provide adequate assurances that he would properly document the treatment of his patients in their charts. However, the Acting Deputy Administrator finds that pursuant to the Stipulation and Order with the state, Respondent's patient charts are currently reviewed on a periodic basis for completeness. As a result the Acting Deputy Administrator finds that Respondent's documentation will be sufficiently monitored. Judge Bittner also concluded that Respondent showed no remorse for his violations of Utah law and continued to assert that despite the medical evidence to the contrary, there was no need to individualize the diet and exercise programs, and that behavioral counseling would be useless. The Acting Deputy Administrator finds that Respondent did show some remorse for his violation of state law and indicated that he acknowledged that what he did was wrong and he would not violate the law in the future. The Acting Deputy Administrator also finds that while Respondent appears reluctant to individualize his weight loss treatment programs as suggested by the medical literature, this does not warrant revocation of his DEA registration.

Judge Bittner concluded ''that the record as a whole establishes that Respondent is unwilling or unable to accept the responsibilities inherent in holding a DEA registration.'' As a result, Judge Bittner concluded that Respondent's continued registration would be inconsistent with the public interest and recommended that Respondent's DEA registration be revoked.

Respondent filed exceptions to Judge Bittner's Opinion and the Government filed a response to Respondent's exceptions which have all been considered by the Acting Deputy Administrator in rendering his decision in this matter. Most of the arguments set forth in these filings have already been addressed in this final order, or it is not necessary to address them in light of the findings of the Acting Deputy Administrator. However, Respondent does argue in his exceptions that Judge Bittner erroneously excluded the October 2, 1997 report of the physician who reviewed Respondent's charts pursuant to the terms of the Stipulation and Order with the state. In its response to Respondent's exceptions, the Government argues that Judge Bittner properly excluded the report since it added nothing to the record in this matter and in order to properly assess the value of the report, the reviewing physician would need to testify and be subjected to cross-examination. This issue will be discussed below.

On August 10, 1999, the record in this matter was transmitted to the Deputy Administrator. On November 4, 1999, Respondent sent a letter to the Deputy Administrator responding to the Government's response to his exceptions and attaching seven reports from the physician who reviewed Respondent's patient charts pursuant to the Stipulation and Order that were generated between October 2, 1997 and September 2, 1999. Respondent recognized that such a filing is not provided for in the regulations, but argued that consideration of it is necessary ''to avoid a gross miscarriage of justice.'' In addition, Respondent filed a formal motion to reopen the record.

The Acting Deputy Administrator finds that Judge Bittner should have reopened the record to allow Respondent to introduce into evidence the October 2, 1997 report from the reviewing physician and to provide the Government with an opportunity to cross-examine the physician and/or introduce rebuttal evidence. Clearly, this report was not available to

Respondent until October 2, 1997, after the conclusion of the hearing in this matter. In addition, the Acting Deputy Administrator finds that this report is clearly material and relevant to the issue in this proceeding. Both Government counsel and Judge Bittner state that the report merely shows that Respondent is complying with the state's Stipulation and Order, which is presumed. However, the Acting Deputy Administrator finds that this report also shows the extent of Respondent's compliance. The issue in this proceeding is whether Respondent's continued registration is inconsistent with the public interest. The state of Respondent's current practice is clearly relevant and this information was not available until after the conclusion of the hearing.

Nonetheless, the Acting Deputy Administrator has decided to deny Respondent's matter to the Administrative Law Judge and has further decided not to remand this matter to the Administrative Law Judge and has further decided to deny Respondent's request to reopen the record dated November 4, 1999, to introduce the October 2, 1997 report of the reviewing physician as well as six subsequent reports. As the Government has stated, in order to admit these reports for reconsideration, the Government would need to be provided with an opportunity to cross-examine the reviewing physician and to possibly introduce rebuttal evidence, which would delay a final decision in this matter. In light of the findings and conclusions set forth in the final order, the Acting Deputy Administrator does not believe that Respondent would want to delay issuance of this decision. Therefore, the seven reports of the reviewing physician attached to Respondent's November 4, 1999 letter have not been considered by the Acting Deputy Administrator in rendering his decision in this matter.

The Acting Deputy Administrator has not considered the other statements made by Respondent in the November 4, 1999 letter. First, such a filing is not permitted by the regulations, and second, they merely reiterate arguments already made by Respondent in his brief and exceptions.

After reviewing the entire record in this matter, the Acting Deputy Administrator concludes that revocation of Respondent's DEA Certificate of Registration is not warranted. The Acting Deputy Administrator does not find that the patients at issue in this proceeding were prescribed controlled substances for no legitimate medical purpose. While Respondent may not have been as careful in prescribing controlled substances and in documenting the reasons for his prescribing, the Acting Deputy Administrator does not believe that revocation is appropriate given the dispute within the medical community as to when it is proper to use controlled substances in weight control.

However, Respondent clearly violated state law by ignoring the 12-week rule and by failing to properly document the treatment of his patients. The Acting Deputy Administrator does not condone Respondent's defiance of state law, but the Acting Deputy Administrator finds it noteworthy that the state is currently monitoring Respondent's treatment of patients and documentation of this treatment; that the state did not restrict Respondent's ability to handle controlled substances based upon the same patient charts in evidence in this proceeding; and that Respondent has taken remedial steps to ensure that he practices in compliance with the law.

But given Respondent's admitted defiance of state law by ignoring the 12-week limitation on prescribing controlled substances for weight control that was in effect at the time of the events at issue, the Acting Deputy Administrator finds that some controls are necessary to ensure that Respondent properly handles controlled substances in the future. Therefore, for two years from the effective date of this final order Respondent shall: (1) Forward to the DEA Salt Lake City office copies of the reports of the physician reviewing his charts pursuant to the Consent Order with the State of Utah; and (2) consent to unannounced inspections by DEA personnel without requiring an administrative inspection warrant.

Accordingly, the Acting Deputy 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) and 0.104, hereby orders that DEA Certificate of Registration AH1650248, previously issued to Wesley G. Harline, M.D., be and it hereby is continued, and subject to the above described restrictions. This order is effective January 27, 2000.

Dated: December 9, 1999.

Julio F. Mercado,

Acting Deputy Administrator.

[FR Doc. 99–33644 Filed 12–27–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 9, 1999, Knoll Pharmaceuticals, 30 North Jefferson Road, Whippany, New Jersey 07981, 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
Dihydromorphine (9145)	I
Hydromorphone (9150)	II

The firm plans to produce bulk product and finished dosage units for distribution to its customers.

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 proposed registration.

Any such comments or objectives may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than February 28, 2000.

Dated: December 16, 1999.

John H. King,

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

[FR Doc. 99–33649 Filed 12–27–99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 21, 1999, Medeva Pharmaceuticals CA, Inc., 3501 West Garry Avenue, Santa Ana, California 92704, 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