

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Withdrawal of Application

By notice dated December 24, 2003, and published in the **Federal Register** on January 27, 2004 (68 FR 39437), Novartis Pharmaceuticals Corporation, Attn: Security Department, Building 103, Room 335, 59 Route 10, East Hanover, New Jersey 07936, made application by renewal to the Drug Enforcement Administration to be registered as a bulk manufacturer of Methylphenidate (1724), a basic class of controlled substance in Schedule II.

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

By letter dated March 11, 2004, the firm stated that it is no longer engaged in the bulk manufacture of this controlled substance. The renewal application for Novartis Pharmaceuticals Corporation is hereby withdrawn.

Dated: April 1, 2004.

William J. Walker,

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

[FR Doc. 04-9328 Filed 4-23-04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of title 21 of the code of Federal Regulations (CFR), this is notice that on February 18, 2004, Penick, Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, 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
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II

The firm plans to manufacture bulk controlled substances and non-controlled substance flavor extracts.

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 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: Federal Register Representative, Office of Chief Counsel (CCD), and must be filed no later than June 25, 2004.

Dated: April 9, 2004

William J. Walker,

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

[FR Doc. 04-9326 Filed 4-23-04; 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 Export Act (21 U.S.C. 958(1)), 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 § 1301.34 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on February 18, 2004, Penick Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, made application by renewal to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed in Schedule II.

Drug	Schedule
Coca Leaves (9040)	II
Raw Opium (9600)	II
Poppy Straw (9650)	II
Concentrate Of Poppy Straw (9670).	II

The firm plans to import controlled substances to manufacture bulk pharmaceutical controlled substances

and non-controlled substance flavor extract.

An manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substances 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 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing 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: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed not later than (30 days from publication).

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(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 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, Office of Diversion Control, 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: April 9, 2004.

William J. Walker,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Merlin E. Shuck, D.V.M.; Revocation of Registration

On January 15, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Merlin E. Shuck, D.V.M. (Respondent), proposing to revoke his DEA Certificate of Registration, AS9668596, pursuant to 21 U.S.C. 824(a)(1) and 824(a)(4) and deny any pending applications for registration as a practitioner under 21 U.S.C. 823(f). The Order to Show Cause alleged that the Respondent's continued

registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and 824(a).

By letter dated February 3, 2003, the Respondent requested a hearing on the matters raised in the Order to Show Cause. On March 14, 2003, Administrative Law Judge Gail A. Randall (Judge Randall) issued an order requiring the Government to file its Pre-hearing Statement on or before March 21, 2003, and the Respondent was to file his Pre-hearing Statement by April 4, 2003.

On March 20, 2003, the Government timely filed its Pre-hearing Statement. However, the Respondent failed to file a Pre-hearing Statement by the date specified by Judge Randall's order. On April 16, 2003, Judge Randall issued a Notice and Order, requiring the Respondent to file his Pre-hearing Statement by May 2, 2003, or in the alternative, the Respondent was to file a status report with Judge Randall indicating his intentions with respect to his request for hearing. Judge Randall further informed the Respondent that failure to respond to the April 16 order would be construed as a waiver of his right to a hearing, resulting in termination of proceedings.

Despite the above notifications, the Respondent failed to file either a Pre-hearing Statement or Status Report. Accordingly, on May 9, 2003, Judge Randall issued an Order Terminating Proceedings, noting that the Respondent's lack of response was considered a waiver of the right to hearing and an implied withdrawal of a request for hearing.

DEA has not received a request for hearing or any other reply from the Respondent or anyone purporting to represent him in this matter. Therefore, the Acting Deputy Administrator finds as follows: (1) Respondent has requested a hearing, (2) the Respondent has been provided an opportunity to participate in such hearing by filing a Pre-hearing Statement and a Status Report, and (3) Respondent has failed to provide any written submissions indicating his intentions with respect to his request for hearing despite several opportunities to submit the same.

The Acting Deputy Administrator concludes that the Respondent is deemed to have waived his hearing right. After considering material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

On October 6, 1997, an opinion of the Supreme Court of Tennessee at Knoxville was issued in conjunction

with a criminal proceeding involving the Respondent. In the opinion, it was found that the Respondent had worked as a practicing veterinarian in Morristown, Tennessee for over thirty years and had been "very active in civic and community affairs." The opinion further recounted that sometime in 1992, the Respondent developed an unusually close and protective relationship with a woman whom he had previously hired to work in his veterinarian clinic as an assistant. It appears from the aforementioned opinion that the Respondent's complicated arrangement with his female employee was reflected in conduct that ranged from the benevolent (*i.e.*, seeking to assist the employee to curb her dependence on alcohol) to the bizarre (repeatedly barging into the employee's apartment unannounced when the latter failed to show for work).

The Respondent's obsessive conduct eventually resulted in his seeking out a "hit man" to murder the female employee, her husband, as well as a male acquaintance of the employee. To that end, on December 16, 1993, the Respondent made a partial payment of five hundred dollars to an individual to help carry out the murders. It was agreed between the two that the individual would bring the employee and her husband to the Respondent, and the Respondent would then kill them by insertion of an unknown drug. However, unbeknown to the Respondent, the "hit man" turned out to be an undercover law enforcement agent for the Tennessee Bureau of Investigation (TBI). The meeting between the Respondent and the undercover agent was videotaped by the TBI. However, before the Respondent could pull off this criminal caper, he was arrested as he left the hotel room where the meeting took place.

On May 21, 1998, the Respondent entered guilty pleas to the offenses of solicitation to commit aggravated kidnapping (two counts) and solicitation to commit first degree murder (one count). The Respondent was subsequently sentenced to a period of incarceration totaling eight years; however, seven years of the sentence were suspended, and the Respondent was placed on supervised probation for seven years.

As a result of the Respondent's criminal convictions, the State of Tennessee, Department of Health, Board of Veterinary Medical Examiners (Veterinary Board) entered an Order dated March 1, 1999, where it placed the Respondent's state veterinary license on five years probation, and ordered the Respondent to pay fine of

\$5,000 as well as perform community service. There is no information in the investigative file regarding any compliance by the Respondent with the probationary conditions placed on his professional license.

On January 7, 2000, the Respondent submitted a renewal application for DEA registration as a hospital (animal shelter). The application was signed and dated by the Respondent. In response to the question 3(d) of the application which asks whether the applicant "ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation * * *, the Respondent provided a "no" response."

The investigative file also contains a second application for registration apparently submitted to DEA in or around March 2001 on behalf of the Respondent. It is unclear whether the second application sought to modify the renewal application, or sought registration at a new location. Nevertheless, the second application listed a proposed registered address different than that for the prior renewal application.

With respect to the March 2001 application, while it appears that a similar "no" response was provided to a question regarding adverse action against a state professional license, the Acting Deputy Administrator finds that this registration application does not appear to be a fully executed document, as it does not contain the required signature of the applicant or the date in which it was completed. The Acting Deputy Administrator is familiar with at least one DEA authority which suggests that a registration application is executed when accompanied by the signature of the applicant. *Hilltop Pharmacy*, 53 FR 35636 (1988). Therefore, having found that the March 2001 application was not properly executed, the Acting Deputy Administrator will not give consideration to the responses provided on the application.

Further review of the investigative file reveals that on November 2, 2000, an unidentified caller inquired with the Nashville DEA office about regulations concerning the administering and storing of controlled substances at a veterinary clinic in Morristown, Tennessee. The caller informed DEA personnel that bottles of sodium pentobarbital, a Schedule II controlled substance, were being stored at the clinic in a safe and a cabinet, and that opened bottles of the substance were being stored in an unlocked wooden cabinet. The caller voiced concerns that the opened bottles of sodium

pentobarbital were easily accessible to employees at the facility and subject to possible abuse. DEA also learned that the clinic in question was not registered with DEA to handle controlled substances and that the sodium pentobarbital was supplied to the facility by the Respondent.

On that same date, a DEA Diversion Investigator telephoned the Respondent regarding the information provided by the unidentified caller. The Respondent admitted that he was familiar with the clinic, that he supervised employees at that facility in their administering of sodium pentobarbital, and that he supplied that facility with the drug. The Respondent further admitted that he was aware that sodium pentobarbital was being stored at the clinic and that the facility was not registered with DEA.

On January 10, 2001, the DEA Nashville office issued a Letter of admonition to the Respondent, informing the Respondent that his distribution of sodium pentobarbital to the unregistered veterinary facility was in violation of 21 U.S.C. 828(a). In a response letter dated May 14, 2001, the Respondent stated in relevant part, that sodium pentobarbital was stored at the unregistered veterinary facility "as a matter of expediency," but that the drug had been kept locked in a safe, under his control.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Acting Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending applications for renewal of such registration, if she 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 or safety.

These factors are to be considered in the disjunctive; the Acting Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See

Henry J. Schwartz, Jr., M.D., 54FR 16,422 (1989).

First, pursuant to 21 U.S.C. 824(a)(1), a registration may be revoked if the registrant has materially falsified an application for registration. DEA has previously held that in finding that there has been a material falsification of application, it must be determined that the applicant knew or should have known that the response given to the liability question was false. See, *James C. LaJavid, D.M.D.*, 64 FR 55962, 55964 (1999); *Martha Hernandez, M.D.*, 62 FR 61,145 (1997); *Herbert J. Robinson, M.D.*, 59 FR 6304 (1994).

As noted above, on March 1, 1999, the Veterinary Board entered an order placing the Respondent's state veterinary license on five years probation, and imposed additional conditions on that license including a fine of \$5,000. Yet a review of the Respondent's DEA renewal application of January 7, 2000, reveals a "no" response to the liability question which asked whether the applicant has ever had a state professional license placed on probation. In light of this evidence, as well as the lack of evidence to the contrary, the Acting Deputy administrator is left to conclude that the Respondent knew or should have known that his "no" response to a liability question on a DEA registration application was false, and therefore, the Respondent materially falsified his application of registration. Accordingly, grounds exist to revoke the Respondent's registration pursuant to 21 U.S.C. 824(a)(1).

Next, the Acting Deputy administrator must consider whether Respondent's continued registration would be inconsistent with the public interest. As to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, as noted above, the Veterinary Board imposed probationary conditions on the Respondent's state veterinary license as a result of his felony criminal convictions. The Acting Deputy administrator finds, that while the Respondent's licensure to practice veterinary medicine and handle controlled substances are not determinative in this proceeding, the imposition of probationary conditions on his professional license nevertheless weigh in favor of a finding that the Respondent's continued registration would be inconsistent with the public interest.

Factors two and four, Respondent's experience in handling controlled substances and his compliance with applicable controlled substance laws, are also relevant in determining the

public interest in this matter. The record in this proceeding reveals that the Respondent stored and dispensed sodium pentobarbital at a non-registered location in Morristown, Tennessee, *i.e.*, the facility was not authorized to order and distribute controlled substances. In addition, the Respondent did not submit DEA 222 order forms when he distributed sodium pentobarbital to a veterinary facility, in violation of 21 U.S.C. 828(a) and 21 C.F.R. 1305.03. Therefore, the Acting Deputy Administrator finds the Respondent's failure to adhere to controlled substance laws and regulations with respect to the distribution and storage of sodium pentobarbital relevant under factors two and four, and also weigh in favor of a finding that his registration would be inconsistent with the public interest.

Factor three, the applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances, is not relevant for consideration here, since there is no evidence that the Respondent has ever been convicted of any crime related to controlled substances.

With respect to factor five, other conduct that may threaten the public health and safety, the Acting Deputy Administrator finds this factor relevant to the Respondent's material falsification of a DEA renewal application, as well as his storage and distribution of controlled substances at an unregistered location. The record in this case further demonstrates that the Respondent executed guilty pleas to the offenses of solicitation to commit aggravated kidnapping and of solicitation to commit first degree murder.

While the above criminal convictions relate to conduct that took place more than ten years ago, the egregious nature of the Respondent's criminal conduct negatively reflects upon his fitness to possess a DEA registration. Criminal conduct unrelated to controlled substances, in particular, matters surrounding a registrant's arrest and conviction, have been relevant in determining the public interest under factor five. *Alexander Drug Company, Inc.*, FR 18299, 18304 (2001). The Acting Administrator also finds factor five relevant to the absence of evidence regarding any compliance by the Respondent with his criminal probation or with the probation imposed by the Veterinary Board.

The Acting Deputy Administrator finds that the Respondent has demonstrated conduct which reflects poor judgment and questionable character. His solicitation for the crime

of murder and kidnapping, and his plan to use drugs to facilitate these crimes is abominable. The Respondent also demonstrated his unfamiliarity with, or refusal to abide by, controlled substance laws and regulations by distributing and storing controlled substances at an unregistered location. Finally, the Respondent falsified an application for DEA registration by his failure to disclose the imposition of probation on his Tennessee state veterinary license. These factors, along with the absence of evidence to the contrary, lead to the conclusion that the Respondent's continued registration would be inconsistent with the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, AS9668596, previously issued to Merlin E. Shuck, D.V.M., be, and it hereby is, revoked. This order is effective May 26, 2004.

Dated: March 29, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 04-9333 Filed 4-23-04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mark G. Stallman, M.D., Denial of Application for Change of Registered Address

On July 18, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mark G. Stallman, M.D. (Dr. Stallman) of Tucker, Georgia, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BS4792102, under 21 U.S.C. 824(a)(2) and (3) and deny his pending application for change of business address, control number C07848305K, pursuant to 21 U.S.C. 823(f). As a basis for revocation, the Order to Show Cause alleged that Dr. Stallman is not currently authorized to practice medicine or handle controlled substances in Georgia, his State of registration and practice. The Order further alleged that his continued registration was inconsistent with the public interest, based on (1) Dr. Stallman prescribing controlled substances that were not in the course of his professional practice, and (2) his April 2, 2003, conviction of eight felony

counts of Illegally Dispensing (Prescribing) a Controlled Substance, in violation of the Georgia Controlled Substances Act, section 16-13-30(b). The Order also notified Dr. Stallman that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Stallman at his address of record at 5745 Lawrenceville Highway, Suite 204, Tucker, Georgia 30084. The Order was also sent by certified mail to Dr. Stallman's attorney, Mr. Barry Zimmerman, 8100-B Roswell Road, Suite 420, Atlanta, Georgia 30350. According to the return receipt, on July 28, 2003, the Order was received by Dr. Stallman's counsel. DEA has not received a request for hearing or any other reply from Dr. Stallman or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Dr. Stallman is deemed to have waived his hearing right. *See Samuel S. Jackson, D.D.S.*, 67 FR 65145 (2002); *David W. Linder*, 67 FR 12579 (2002). After considering material from the investigative file, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Stallman currently possesses DEA Certificate of Registration BS4792102, expiring February 28, 2005, to handle Schedule II through V controlled substances. On January 2, 2002, he filed an application, assigned DEA control number C07848305K, requesting registration at a different address than his current registered location.

The Deputy Administrator further finds that, effective June 2, 2003, the Composite Board of Medical Examiners for the State of Georgia (Board) issued its Final Decision, approving the Initial Decision of an Administrative Law Judge recommending the indefinite suspension of Dr. Stallman's Georgia medical license. That suspension was based upon the finding of fact, *inter alia*, that on August 12, 1999, Dr. Stallman's license to practice medicine in the State of Illinois was suspended indefinitely by the Illinois Department of Professional Regulation as a result of his participation in a scheme to process fraudulent personal injury claims.

The investigative file contains no evidence that the Georgia Board's Final Decision has been modified or stayed or that Dr. Stallman's medical license in that State has been reinstated.

Therefore, the Deputy Administrator finds that Dr. Stallman is not currently authorized to practice medicine in the State of Georgia. As a result, it is reasonable to infer he is also without authorization to handle controlled substances in that State.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without State authority to handle controlled substances in the State in which he conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See Muttaiya Darmarajeh, M.D.*, 66 FR 52936 (2001); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *Bobby Watts, M.D.*, 53 FR 11919 (1988).

Here, it is clear Dr. Stallman's medical license has been suspended and he is not currently licensed to handle controlled substances in Georgia, where he is registered with DEA. Therefore, he is not entitled to a DEA registration in that State. Because Dr. Stallman is not entitled to a DEA registration in Georgia due to his lack of State authorization to handle controlled substances, the Deputy Administrator concludes it is unnecessary to address whether his registration should be revoked based upon the other grounds asserted in the Order to Show Cause. *See Fereida Walker-Graham, M.D.*, 68 FR 24761 (2003); *Nathaniel Aikins-Afful, M.D.*, 62 FR 16871 (1997); *Sam Moore, D.V.M.*, 58 FR 14428 (1993).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BS4792102, issued to Mark G. Stallman, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that the pending application for a change of registered location and any other pending applications for renewal or modification of Dr. Stallman's registration be, and they hereby are, denied. This order is effective May 26, 2004.

Dated: April 7, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04-9330 Filed 4-23-04; 8:45 am]

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