- Long Range Transportation Plan.
- Headlands Institute Improvements and Expansion Plan.
- USCG Lighthouses Transfer Update.
- Trails Forever—Update on Projects.
- Headlands Institute Campus Improvement and Expansion Plan.
- Activities and membership information of the Golden Gate National Parks Conservancy.
- Update on Park Partner Projects in the Marin Headlands.
- Update on Restroom Construction at Fort Funston.
- Ocean Beach: Erosion Control and Vision Planning.
- Update on Institute at Golden Gate.
- Accessibility projects and goals at GGNRA.
- Update on GGNRA's San Mateo Lands.

Specific final agendas for these meetings will be made available to the public at least 15 days prior to each meeting and can be received by contacting the Office of Public Affairs, Golden Gate National Recreation Area, Building 201, Fort Mason, San Francisco, California 94123 or by calling (415) 561–4733. They are also noticed on the Golden Gate National Recreation Area Web site *http://www.nps.gov/goga* under the section ''Public Meetings''.

All Open Houses are open to the public. Sign language interpreters are available by request at least one week prior to a meeting. The TDD phone number for these requests is (415) 556 2766. For copies of the agendas contact the Office of Public Affairs, Golden Gate National Recreation Area, Building 201, Fort Mason, San Francisco, California 94123, or call (415) 561–4733.

Dated: December 8, 2008.

Brian O'Neill,

General Superintendent, Golden Gate National Recreation Area.

[FR Doc. E8–31157 Filed 1–5–09; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Wonderyears, Inc.; Denial of Application

On December 17, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Wonderyears, Inc. (Respondent), of Deerfield Beach, Florida. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration as a retail pharmacy on the ground that its registration ''would be inconsistent with the public interest.'' Show Cause Order at 1.

The Show Cause Order specifically alleged that on January 10, 2007, Daniel L. Dailey, Respondent's President and Chief Executive Officer, had applied for a DEA pharmacy registration to dispense controlled substances in schedules II through V. *Id.* The Show Cause Order alleged, *inter alia*, that Dailey had previously been the President and CEO of Powermedica, an entity which had held a DEA registration as a retail pharmacy, and that on several occasions, Special Agents of the Food and Drug Administration had obtained from Powermedica, anabolic steroids, which are schedule III controlled substances, without having any contact with a physician, in violation of federal and state laws. *Id.* at 2 (citing 21 U.S.C. 841; 21 CFR 1306.04, Fla. Stat. Ann. § 465.015(2)(c)).

On December 26, 2007, the Show Cause Order, which also notified Respondent of its rights under 21 CFR 1301.43, was served on it by certified mail to the address of its proposed registered location. Since that date, neither Respondent, nor anyone purporting to represent it, has requested a hearing. Because more than thirty days have elapsed since Respondent was served with the Show Cause Order, and Respondent has not requested a hearing, I conclude that Respondent has waived its right to a hearing. 21 CFR 1301.43(d). I therefore enter this Decision and Final Order based on relevant material contained in the investigative file and make the following findings.

Findings

Respondent is a Florida Corporation whose President is Daniel L. Dailey. On January 10, 2007, Respondent submitted an application for a DEA Certificate of Registration as a retail pharmacy and sought authority to handle controlled substances in schedules II through V, at the proposed location of 270 SW 12th Ave., Deerfield Beach, Florida. Respondent's application was prepared by Daniel L. Dailey.

On March 16, 2007, DEA Diversion Investigators (DIs) went to Respondent's principal place of business (which was an address different than that listed on its application) to conduct a pre-registration investigation and met with Dailey. Dailey, who was the only corporate officer of the entity, provided the DIs with a copy of Respondent's Articles of Incorporation and told the DIs that it would compound veterinary medications for swines and equines. Respondent, however, held only a community pharmacy license from the State of Florida and Dailey told the investigator that he had not even applied to the State for a compounding pharmacy license. Dailey further maintained that he would not compound steroids, but rather, only non-controlled medications such as creams and gels.

A week later, Dailey telephoned one of the DIs and told her that he now needed a DEA registration because he was seeking a contract with two AIDS clinics. He also stated that he planned to sell controlled substances to physicians.

Dailey further told the DI that he had first become involved in the pharmaceutical business in November 2000, when he invested Powermedica, Inc. According to the records of the State of Florida, as well as a letter he submitted to the DI, Dailey ''was the President and CEO of a company Powermedica, Inc.[,] which was the subject of [an] FDA investigation in 2005.'' In the letter, Dailey further stated that Powermedica had ''not been charged or fined by the Federal Authorities.''

According to the investigative file, on June 20, 2005, the Florida Department of Health ordered the emergency suspension of the pharmacy permit held by Powermedica, Inc. *See* Order of Emergency Suspension of Permit, *In re: The Emergency Suspension of the Permit of PowerMedica, Inc.,* 1 (Fla. Dep't Health, 2005). The order found that ''at all times material to [the] cases, Daniel L. Dailey was chief executive of Powermedica.'' *Id.* at 2. The order further found that on August 13, 2004, an FDA Special Agent (S/A) had visited Powermedica's Website and made an undercover purchase of stanozol (4 mg.), an anabolic steroid and schedule III controlled substance, by ''complet[ing] a brief medical questionnaire,'' and entering some personal information including a ''mailing address and credit card authorization.'' *Id.* at 3. On August 18, 2004, the FDA S/A received the stanozol. *Id.* at 4. The accompanying prescription listed the prescribing physician as Dr. Abi Almarashi. *Id.* Almarashi, whose office was located in Flushing, New York, had ''never performed a physical examination of'' the S/A and had never discussed with her ''treatment options and the risks and benefits of treatment.'' *Id.*[1]

The same day, another FDA S/A visited the Powermedica Web site and made an undercover purchase of

[1] According to the investigative file, Powermedica's Web site advertised that the company offered for sale various anabolic steroids.

another anabolic steroid and schedule III controlled substance, nandrolone decanoate (100 mg.), by ''complet[ing] a brief medical questionnaire'' and entering his mailing address and credit card information. *Id.* at 4. On August 25, 2004, the S/A received the nandrolone and a prescription sheet which authorized three refills. *Id.* The S/A ''did not have a physical examination nor did he speak to a doctor regarding this prescription at any time before receipt of the medication.'' *Id.*

Subsequently, one of the FDA S/As, who had since visited Powermedica's office and purchased human growth hormone (HGH), introduced a Detective from the Broward County, Florida Sheriff's Office to Tony Jones, who represented that he was a ''clinical consultant'' for Powermedica.[2] *Id.* at 9. The Detective, who was attempting to make an undercover purchase of Powermedica's Testosterone Replacement Therapy, which included both testosterone cypionate, an anabolic steroid and schedule III controlled substance, and human chorionic gonadotropin, a non-controlled drug, subsequently met with Jones, completed a questionnaire, and paid him $175 for a lab test and ''doctor's fee.'' *Id.* Approximately two weeks after he underwent a blood test, the Detective went to Powermedica's office and picked up his order which contained 200 mg./ml. of testosterone cypionate, needles and syringes.[3] *Id.* at 11. The Detective paid $312.10 for his order. *Id.* Powermedica distributed the drugs to the Detective notwithstanding that the Detective had not been physically examined by a physician and no physician had discussed with him the risks and benefits of using testosterone cypionate. *Id.*

Following the service of the suspension order, Powermedica did not contest the State's findings. Nor did it contest the allegations of the administrative complaints which the State subsequently filed. Instead, it voluntarily relinquished its pharmacy permits. *See* Final Order of Voluntary Relinquishment, *Department of Health* v. *Powermedica, Inc.* (Sept. 15, 2005). On September 18, 2005, Powermedica also surrendered its DEA registration.[4]

Discussion

Section 303(f) of the Controlled Substances Act provides that ''[t]he Attorney General may deny an application for [a pharmacy] registration if he determines that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the Act requires the consideration of the following factors:

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

(2) The applicant's experience in dispensing * * * 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.

Id.

''[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.'' *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005).

While Respondent is a corporate entity and technically has an independent legal existence from its officers, DEA has long held that misconduct committed by a corporation's officers and owners (in the case of a closely held corporation) is properly considered in determining whether to revoke an existing registration, or deny an application for a new registration, of a corporate entity. *See MB Wholesale, Inc.,* 72 FR 71956, 71958 (2007); *Lawson & Sons Pharmacy,* 48 FR 16140, 16141 (1983). In light of Mr. Dailey's ownership of, and role as CEO of Powermedica, and his ownership of, and role as CEO of Respondent, I hold that Powermedica's experience in dispensing controlled substances and record of compliance with Federal and State laws related to controlled substances is properly considered in determining whether granting Respondent's application would be inconsistent with the public interest.

As found above, Powermedica unlawfully distributed anabolic steroids including stanozol, nandrolone decanoate, and testosterone cypionate, which are schedule III controlled substances, on multiple occasions. The distributions were unlawful because they were based on prescriptions issued by a physician who did not establish a legitimate doctor patient relationship with the undercover officers and Dailey/Powermedica had reason to know that the prescriptions were illegal. Indeed, the evidence shows that the undercover officers had no contact at all with Dr. Almarashi and that the officers' information was routed by Dailey/Powermedica to Almarashi in order to obtain the prescriptions necessary to dispense the steroids.

As the State noted in the emergency suspension order, Fla. Sta. § 465.023(1)(e) ''prohibits a pharmacy permittee from dispensing any medicinal drug based upon [a] prescription when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that included a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed.'' Order of Emergency Suspension at 16 (para. 58). These distributions likewise violated the CSA. *See* 21 CFR 1306.04(a) (''A prescription for a controlled substance * * * 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.'').

Moreover, Dr. Almarashi was licensed in New York and maintained his office in Flushing, New York. Yet he was prescribing to persons in Florida, where he was not licensed. As previously noted, a prescription issued by a practitioner who is engaged in the unauthorized practice of medicine is not a prescription which has been issued in

[2] The investigation also revealed that Powermedica distributed HGH to the FDA S/A and a Detective from the Miami-Dade Police Department based on prescriptions issued by Dr. Almarashi. Almarashi did not physically examine either the S/A or the Detective, and had not discussed the risks and benefits of using HGH with either officer. *Id.* at 6. Moreover, the FDA agents subsequently seized HGH which had been shipped to Powermedica from a non-FDA approved manufacturer in China; these imports violated the Food, Drug and Cosmetic Act, and the Florida statutes. *Id.* at 10–11. While HGH is not a controlled substance, Powermedica's violations of federal and state laws in distributing and importing this drug are relevant in assessing whether it would comply with the Controlled Substances Act.

[3] The Detective was also given a bag of Somatropin 6 mg. along with needles and syringes. *Id.* at 11.

[4] During the investigation of his new firm's application, Dailey asserted that a Special Agent had lied to a magistrate about obtaining controlled substances without prescriptions. Dailey's assertion begs the question of why he surrendered Powermedica's state license without contesting the allegations against it which were contained in the various complaints brought by the State.

the usual course of professional practice. *See* 21 U.S.C. 802(21) (''The term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance.''); *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) (''In the case of a physician, the [CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.''); *see also United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007) (''[A] physician who engages in the unauthorized practice of medicine under state laws is not a 'practitioner acting in the usual course of * * * professional practice' under the CSA.'').

I therefore conclude that Mr. Dailey's/Powermedica's experience in dispensing controlled substances (factor two) and his/its record of non-compliance with applicable Federal and State laws (factor four) amply demonstrate that granting Respondent's application for a new registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f).[5] Accordingly, Respondent's application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) & 0.104, I order that the application of Wonderyears, Inc., for a DEA Certificate of Registration as a retail pharmacy be, and it hereby is, denied. This Order is effective February 5, 2009.

Dated: December 19, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–31414 Filed 1–5–09; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–8]

Jayam Krishna-Iyer, M.D.; Suspension of Registration; Granting of Renewal Application Subject to Condition

On September 1, 2006, I, the Deputy Administrator of the Drug Enforcement Administration, ordered that the DEA Certificate of Registration issued to Jayam Krishna-Iyer, M.D. (Respondent), of Clearwater, Florida, be revoked. *Jayam Krishna-Iyer, M.D.*, 71 FR 52148, 52159 (2006). The Order also denied Respondent's pending application for renewal of her registration.

As grounds for the Order, I noted that Respondent had issued prescriptions for controlled substances to three separate undercover operatives notwithstanding that each of the operatives had indicated that he was not in pain, and had told Respondent that he was obtaining controlled substances from non-legitimate sources such as friends. *Id.* at 52158. I further noted that Respondent had failed to conduct a physical exam on each of the undercover operatives and had falsified each operative's medical record to indicate that she had done an exam. *Id.* I also noted that Respondent had made statements during each operative's visit indicating that she knew that the operative was seeking the drugs to abuse them and not to treat pain. *Id.* Finally, I noted that Respondent had pre-signed prescriptions and given them to a registered nurse in her employ, and that she allowed the nurse to issue prescriptions to one of the operatives even though she did not attend to the operative during the visit and the nurse lacked authority under both Federal law and Florida law to prescribe controlled substances. *Id.*

In the decision, I noted that Respondent had undertaken substantial measures to reform her practice including hiring a private investigation firm to review patient records to determine which patients were likely substance abusers and should be discharged from her practice; the firm also developed procedures for recognizing drug abusers, doctor shoppers, prescription fraud, patients with a drug-related criminal history, and dealing with claims of lost and stolen medications. *Id.* at 52156. I also noted that the firm had conducted extensive criminal history checks on Respondent's patients and that she had discharged a large of number of patients. *Id.*

While I recognized the substantial measures that Respondent had undertaken to reform her practice, I adopted the ALJ's finding that Respondent failed to accept responsibility for her misconduct based on her testimony that she did not intentionally or knowingly distribute a controlled substance to the undercover operatives because she knew the drugs would not be sold on the street. *Id.* at 52159. As I explained in the Order, ''[i]t is no less a violation that the 'patient' will personally use the drug rather than sell it on the street.'' *Id.* I further concluded that because Respondent had ''refuse[d] to acknowledge her responsibilities under the law,'' the reforms she had undertaken would ''still not adequately protect public health and safety,'' and that this finding was dispositive as to whether her continued registration would be consistent with the public interest. *Id.*

Thereafter, Respondent filed a petition for review in the U.S. Court of Appeals for the Eleventh Circuit. On September 25, 2007, following briefing and oral argument, the Court vacated the Agency's Order in an unpublished opinion. *Krishna-Iyer* v. *DEA*, No. 06–15034 (11th Cir. 2007), Slip Op. at 3. The Court declared:

> In considering Petitioner's experience in dispensing controlled substances under factor 2, the DEA identified only four visits by three undercover 'patient,' who were all attempting to make a case against her. The DEA failed to consider Petitioner's experience with twelve patients whose medical charts were seized by the DEA, or with thousands of other patients. In short, the DEA did not consider any of Petitioner's positive experience in dispensing controlled substances. This is an arbitrary and unfair analysis of Petitioner's experience.

Id. The Court therefore vacated the Order and remanded the case for reconsideration, directing that ''DEA should pay particular attention to the entire corpus of Petitioner's record in dispensing controlled substances, not only the experience of [the] undercover officer.'' *Id.* The Court further ordered that ''[t]he five factors should * * * be re-balanced.'' *Id.*

On September 15, 2008, the Parties submitted a joint motion which proposed a resolution of the matter. More specifically, the Parties propose that I ''issue a new final Order consistent with the direction of the * * * Court of Appeals.'' Joint Motion at 2. The Parties also request that were I to find that ''revocation or suspension is still an appropriate outcome,'' that the sanction be limited ''to suspension of [her] registration for the time'' that the Final Order remained in effect. The Parties also requested that I direct that Respondent's pending renewal application be acted upon expeditiously. Finally, the Parties represented that if I concurred with their proposed resolution, they would enter into a Memorandum of Agreement (MOA) under which Respondent's registration will be renewed subject to the condition that for a one year period, she file monthly reports with the Agency's Miami Field Division providing information regarding her prescribing of controlled substances.

Attached to the Joint Motion was Respondent's statement. In her

[5] In light of my findings with respect to factors two and four, I conclude that it is unnecessary to make findings with respect to the remaining factors.