

outlined that Respondent's intended customers were "Medical Patients" referred under California's Compassionate Use Act of 1996.

The Government argued, *inter alia*, that California law requires the Respondent to obtain state licenses to manufacture marijuana or THC for human consumption, pursuant to the Consumer Product Safety Section, California Department of Health Services, and from the State Board of Pharmacy. In support of its argument, the Government attached to its motion a declaration from Susan Bond, Section Chief of the Consumer Product Safety Section, Department of Health Services, Food and Drug Branch for the State of California. Ms. Bond stated that a state license to manufacture marijuana and THC was required under California Health and Safety Code Section 111615, and according to state records, the Respondent neither held such license, nor submitted an application to obtain such license. Ms. Bond concluded that the Respondent did not possess valid state authority in California to manufacture marijuana or THC for medical use in that state. The Government also attached eight Certifications of Non-Licensure, in which the Executive Officer for the California Board of Pharmacy certified that Respondent was not currently licensed with the California Board of Pharmacy.

In response to the Government's motion, the Respondent highlight its participation in various research projects, specifically in the area of whole plant utilization. However, the Respondent did not dispute that it currently lacks state authorization to manufacture marijuana and THC. The Respondent further argued that the granting of the Government's motion would be premature, impede future research, deny the Respondent the right to a fair trial, and cause irreparable injury to the Respondent's patients and associates.

Pursuant to 21 U.S.C. 823(a), DEA shall register an applicant to manufacture controlled substances in Schedule I or II if it determines that such registration is consistent with the public interest. Included among the six public interest factors is "compliance with applicable State and local law." 21 U.S.C. 823(a)(2). In addition 21 CFR 1307.02 provides that DEA will not authorize any person "to do any act which such person is not authorized or permitted to do under * * * the law of the State in which he/she desires to do such act."

Section 823(a) contains no express threshold requirement of state

authorization. Nonetheless, DEA has previously determined that where as here state law requires manufacturers of controlled substances to obtain a state license, it would be pointless to grant a Federal registration when the Respondent lacked state authority. Michael Schumacher, 60 FR 13171 (1995); see also Church of the Living Tree, 63 FR 69,674 (1998).

In her Opinion and Recommended Ruling, Judge Randall agreed with the Government that state licenses are required in California prior to manufacturing marijuana or THC. Judge Randall found that consistent with DEA regulations, as well as the agency's discussions in Michael Schumacher and Church of the Living Tree, DEA will not authorize the Respondent to engage in the manufacture of a Schedule I controlled substance in California since the Respondent lacks authority from that state to conduct such an activity. Therefore, Judge Randall concluded that summary disposition was proper.

The Deputy Administrator concurs with the Administrative Law Judge's grant of the Government's Motion for Summary Judgement. It is well settled, that when no question of material fact is involved, or when the material facts are agreed upon, a plenary, adversary administrative proceeding involving evidence and cross-examination of witnesses is not obligatory. See Gilbert Ross, M.D., 61 FR 8664 (1996); Philip E. Kirk, M.D., 48 FR 32,887 (1983), *aff'd sub nom Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); *NLRB v. International Association of Bridge, Structural and Ornamental Ironworkers, AFL-CIO*, 549 F.2d 634 (9th Cir. 1977).

The Deputy Administrator also finds, and the parties do not dispute, that the State of California requires a manufacturer of marijuana or THC to obtain state licenses before engaging in such activity. It is clear from the record in this proceeding that the Respondent is not licensed as a manufacturer of Schedule I controlled substances in California. Thus, as Judge Randall noted, there is no material question of fact in dispute concerning this aspect of the case. Because the Respondent does not meet a necessary precondition for DEA registration, a hearing in this matter is unnecessary. Therefore, Respondent's pending application for DEA Certificate of Registration must be denied.

In its motion, the Government further argued that the Respondent's application should be denied because marijuana and THC have no accepted medical use under the Controlled Substances Act. However, as noted above, DEA has indicated in previous

final orders that an application to manufacture marijuana would be denied if the Respondent lacked state authority for such activity. Because the Respondent is not entitled to a DEA registration due to its lack of state authorization to manufacture Schedule I controlled substances in California, the Deputy Administrator concludes that it is unnecessary to address whether Respondent's application for DEA registration should be denied based upon the other grounds asserted in the Order to Show Cause and the Government's Motion for Summary Judgement. See Samuel Silas Jackson, D.D.S., 67 FR 65145 (2002); Nathaniel-Aikens-Afful, M.D., 62 FR 16871 (1997).

Accordingly, the 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 the application for DEA Certificate of Registration submitted by Genesis 1:29 Corporation, be, and it hereby is, denied. This order is effective April 28, 2003.

Dated: March 13, 2003.

John B. Brown III,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Lazaro Guerra, M.D.; Denial of Application for Registration

This order serves as a correction of the final order previously issued in this matter and published on November 12, 2002.

On February 25, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Lazaro Guerra, M.D. (Dr. Guerra) of Hialeah, Florida, notifying him of an opportunity to show cause as to why DEA should not deny his application for a DEA Certificate of Registration pursuant to 21 U.S.C. 824(a). As a basis for revocation, the Order to Show Cause alleged that Dr. Guerra is not currently authorized to handle controlled substances in Florida, the state in which he practices, and that he has been permanently excluded from the Medicare program. The order also notified Dr. Guerra 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. Guerra at both his

registered location in Hialeah, Florida and to the Federal Detention Center in Miami, Florida, where Dr. Guerra was incarcerated. DEA received signed receipts indicating that the Order to Show Cause was received on Dr. Guerra's behalf on March 5, 2002, at the Federal Detention Center and on March 4, 2002, at his registered address. DEA has not received a request for hearing or any other reply from Dr. Guerra 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. Guerra is deemed to have waived his hearing right. After considering material from the investigative file in this matter, the Deputy Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Administrator finds that on March 11, 2001, Dr. Guerra submitted an application for DEA Certificate of Registration as a researcher, seeking authorization to handle controlled substances in Schedule I at a hospital facility in Hialeah, Florida.

On February 10, 2000, Dr. Guerra, along with two other individuals, were charged through a criminal information in the United States District Court, Southern District of Florida with conspiracy to commit mail fraud. Specifically, Dr. Guerra and others were charged with using fraudulent means to obtain approximately \$2.7 million from Medicare in the form of reimbursements from 1990 to January 1997. On April 10, 2001, Dr. Guerra entered a guilty plea to one felony count of mail fraud. As part of his plea, he agreed to pay \$2.7 million in restitution to the United States Department of Health and Human Services. He was sentenced to forty-eight (48) months imprisonment, and ordered to pay additional fines and assessments. He further agreed to a permanent mandatory exclusion from participation in the Medicare program pursuant to 42 U.S.C. 1320a-7(a). Such exclusion is an independent ground for revoking a DEA registration. 21 U.S.C. 824(a)(5).

Moreover, on July 18, 2001, the Florida Department of Health issued an Order of Emergency Suspension of License with respect to Dr. Guerra's medical license. The suspension of his medical license has not been lifted. Therefore, Dr. Guerra is not currently authorized to handle controlled substances in the State of Florida. Therefore, she is not entitled to a DEA

registration in that state. 21 U.S.C. 824(a)(3).

Accordingly, the 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 Dr. Guerra's application for DEA registration be, and hereby is, denied. The Deputy Administrator further orders that any other pending applications from Dr. Guerra be, and hereby are, denied. This order is effective April 28, 2003.

Dated: March 6, 2003.

John B. Brown III,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 00-24]

Robert A. Leslie, M.D., Revocation of Registration

On May 8, 2000, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Robert A. Leslie, M.D. (Respondent), proposing to deny his application for a DEA Certification of Registration pursuant to 21 U.S.C. 823(f) for reason that such registration would be inconsistent with the public interest. Specifically, the Order to Show Cause alleged the following:

(1) On August 17, 1990, Respondent's DEA Certificate of Registration, ALOO33186, was revoked based in part on findings that: (a) On or about October 3, 1986, Respondent was convicted in the Superior Court for the County of Los Angeles, California of eight counts of unlawfully prescribing, administering, furnishing, or dispensing controlled substances; and (b) effective March 23, 1990, the California Board of Medical Quality Assurance suspended Respondent's license to practice medicine for ninety days and placed his medical license on probation for five years.

(2) During February 1992, Respondent submitted a new application for registration. Following a hearing, the then-Administrator of DEA denied Respondent's application, effective March 15, 1995, noting, *inter alia*, that Respondent was either unable or unwilling to discharge the responsibilities inherent in a DEA registration. Respondent's petition for review of this decision was denied by

the United States Court of Appeals for the Ninth Circuit on August 5, 1996.

(3) On or about December 13, 1996, Respondent submitted a new application for a DEA registration. The then-Deputy Administrator concluded that the previous administrative proceeding was *res judicata* for the purposes of the then-current proceeding. Effective June 14, 1999, the Deputy Administrator again denied Respondent's application, concluding that other than the passage of time, the circumstances existing at the time of the prior proceeding had not sufficiently changed to warrant issuance of a DEA registration.

Respondent, acting *pro se*, filed a timely request for a hearing on the issues raised in the Order to Show Cause. Following prehearing procedures, a hearing was held on September 21, 2000, and February 8, 2001, in Los Angeles, California before Administrative Law Judge Mary Ellen Bittner (Judge Bittner). At the hearing, the Government called two witnesses to testify and the Respondent testified on his own behalf. Both parties also introduced documentary evidence. After the hearing, both parties submitted proposed findings of fact, conclusions of law, and argument.

On August 2, 2001, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision recommending that the Respondent's application be denied. On or around August 17, 2001, the Respondent timely filed exceptions to Judge Bittner's recommended ruling. Thereafter, Judge Bittner transmitted the record of these proceedings to the Administrator of the Drug Enforcement Administration.

On March 4, 2002, the Respondent filed Judge Bittner, a letter (the March 2002 letter) in which he represented, among other things, that a provision under California law allows physician assistants to prescribe certain drugs "with or without preprinted prescriptions from the supervising physician." The Respondent further requested that Judge Bittner transmit the additional document to the Deputy Administrator for consideration. It appears from a review of the record before the Deputy Administrator that matters involving the role of physician assistants and the prescribing of controlled substances were litigated. It is unclear however why the Respondent did not introduce the March 2002 at the hearing or reference its contents in his post-hearing submissions. Therefore, in rendering his decision in this matter, the Deputy Administrator has not considered the Respondent's untimely