

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