

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of

Docket No. 02-15

Genesis 1:29 Corporation

OPINION AND RECOMMENDED RULING OF THE ADMINISTRATIVE

LAW JUDGE

Gail A. Randall, Administrative Law Judge

APPEARANCES:

Steve Sola, Esq.
Counsel for the Government

Robert Schmidt, CEO
Pro se

DATED: June 26, 2002

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**OPINION AND RECOMMENDED RULING
OF THE ADMINISTRATIVE LAW JUDGE**

I. BACKGROUND

By Order dated December 13, 2001, the Deputy Assistant Administrator of the Drug Enforcement Administration ("DEA") notified Genesis 1:29 Corporation ("Respondent") of an opportunity to show cause as to why the DEA should not deny its pending application for a DEA Certificate of Registration. The DEA asserted that granting the application would be inconsistent with the public interest. On January 22, 2002, the Respondent requested a hearing in this matter. On January 25, 2002, I ordered the parties to file their pre-hearing statements, and both the Government and the Respondent filed such statements.

On April 30, 2002, the Government filed its Request for Stay of Proceedings and Motion for Summary Judgment ("Motion"), alleging that the Respondent lacks state authority to engage in the activity for which it seeks registration. The Government further argues that the Respondent applied for a DEA registration solely as a manufacturer, when it should have additionally applied as a researcher, given the Respondent's intended activities involving scheduled substances. In light of these arguments, the Government contends that summary judgement is appropriate, that there is no need for a hearing, and that Respondent's application should be denied.

By order dated May 2, 2002, I granted a stay in these proceedings and provided the

Respondent an opportunity to respond to the Government's motion. On June 6, 2002, the Respondent filed his response. ("Response").

II. FINDINGS OF FACT

By application of registration dated September 11, 2001, the Respondent applied for a DEA Certificate of Registration as a manufacturer of bulk and dosage form marihuana and tetrahydrocannabinol ("THC"), both Schedule I substances.¹ The DEA submitted a list of questions to the Respondent, and, in reply, the Respondent informed the DEA that its purpose was to supply the Schedule I substances for human consumption.²

In the Motion, the DEA asserted that California law requires the Respondent to obtain state licenses to manufacture marihuana or THC for human consumption, specifically from the Consumer Product Safety Section, California Department of Health Services, and from the State Board of Pharmacy. [Motion at 7]. In support of this assertion, the Government attached the Declaration of Susan Bond, Section Chief, Consumer Product Safety Section, Department of Health Services, Food and Drug Branch, State of California. Ms. Bond declared that such a state license was required by the California Health and Safety Code Section 111615. She further wrote that she had checked the agency's database, and that the Respondent had not submitted an application for such a license, nor did it currently hold such a license. She concluded:

¹ The application references drug code 7360, which is marihuana, and 7370, which is tetrahydrocannabinol. *See* 21 C.F.R. 1308.11 (d) (19) and (27) (2001).

² In its Motion, the DEA also discussed documents it had received which noted that the Respondent also intended to engage in research involving the human consumption of marihuana. The Government correctly noted that the Respondent would need to submit another application for registration which meets the requirements for obtaining a DEA Certificate of Registration authorizing such research. Since such an application is not pending before me at this time, I will not address the research issues in this Opinion.

“Therefore, these entities do not possess valid state authority in California to manufacture marijuana or THC for medical use in California.” [Motion, attachment 3]. The Government also attached eight Certifications of Non-Licensure, in which Patricia Harris, Executive Officer, California State Board of Pharmacy, certified that the Respondent was not currently licensed with the California State Board of Pharmacy. [Motion, Attachment 4].

In the Response, the Respondent did not deny or refute the state licensing requirement. Further, the Respondent wrote that it was “in the process (of) registering with the appropriate State agencies.” [Response at 1-2].

III. DISCUSSION

Pursuant to 21 U.S.C. § 823 (a), the 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. The statute lists six factors to consider in determining the public interest, to include “compliance with applicable State and local law.” 21 U.S.C. § 823(a)(2). Further, 21 C.F.R. § 1307.02 provides that the 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.” 21 C.F.R. §1307.02 (2001).

Pursuant to California legislation, the Respondent is required to obtain state licenses prior to manufacturing marijuana or THC in that state. [Motion, attachment 3]. The Respondent admits that it does not possess such licenses. [Response at 2]. Therefore, the Respondent lacks California state authority to manufacture marijuana or THC. Consistent with the DEA’s regulations, then, the DEA will not authorize this Respondent to engage in the manufacturing of a Schedule I substance in California, since the Respondent lacks authority from California to conduct such an activity.

Similarly, in *Michael Schumacher*, the Deputy Administrator denied an application for a DEA Certificate of Registration for a manufacturer, because, in part, the applicant lacked state authority to handle controlled substances. *Michael Schumacher*, 60 Fed. Reg. 13,171 (DEA 1995). In that final order, the Deputy Administrator adopted the opinion of the Administrative Law Judge, writing that the:

administrative law judge noted that 21 U.S.C. § 823(a), the provision requiring registration of manufacturers of Schedule I and II controlled substances, contains no express threshold requirement of state authorization. Nonetheless, she concluded 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 Respondent lacked state authority.

Id. at 13,171 - 13,172.

Here, the Respondent is not authorized by the State of California to manufacture marihuana, lacking the applicable state licenses. Thus, consistent with the agency's discussions in *Michael Schumacher*, the DEA should deny this Respondent's application.³ See *Michael Schumacher*, 60 Fed. Reg. at 13,172; see also *Church of the Living Tree*, 63 Fed. Reg. 69,674 (DEA 1998).

It is well settled that where there is no material question of fact involved, or when the facts are agreed upon, there is no need for a plenary, administrative hearing. Congress did not intend for administrative agencies to perform meaningless tasks. *Gilbert Ross, M.D.*, 61 Fed.

³ In the Motion, the Government also asserted that the Respondent's application should be denied because marihuana and THC have no accepted medical use under the Controlled Substances Act. [Motion at 7, 10-12]. However, since the DEA has indicated in the past that an application to manufacture marihuana would be denied if the Respondent lacked state authority for such activity, I rely upon that basis to reach the conclusion in this case. Accordingly, I will not reach the Government's alternative argument concerning medical use of marihuana. Although such an argument may have merit, this matter is more clearly resolved relying upon existing DEA regulations and precedent.

Reg. 8664 (1996); *Dominick A. Ricci, M.D.*, 58 Fed. Reg. 51,104 (1993); *Philip E. Kirk, M.D.*, 48 Fed. Reg. 32,887 (1983), *aff'd sub nom Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984). Here, there is no dispute that the State of California requires a manufacturer of marihuana or THC to obtain state licenses. Further, the parties do not dispute that the Respondent does not have such licenses. Thus, there is no material question of fact in dispute concerning this aspect of the case.

IV. CONCLUSION AND RECOMMENDATION

The Respondent is required to have California state licenses to manufacture marihuana or THC. He does not possess such licenses. Consistent with the agency's regulations and discussion in *Michael Shumacher*, the DEA should deny this Respondent's DEA application at this time. *See Michael Shumacher*, 60 Fed. Reg. at 13,172; *Church of the Living Tree*, 63 Fed. Reg. at 69,674.

The parties do not dispute that the State of California requires a manufacturer of marihuana or THC to obtain state licenses, and that the Respondent does not have such licenses. Therefore, since there is no dispute over any material facts, summary disposition is appropriate in this matter. Accordingly,

I therefore GRANT the Government's Motion for Summary Disposition.

I will also return the case file to the Deputy Administrator, recommending that he deny the Respondent's pending application for a DEA Certificate of Registration to manufacture marihuana and THC.

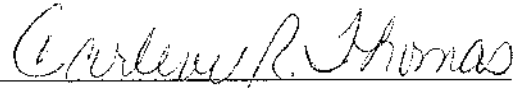
Dated: June 26, 2002



Gail A. Randall
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned on June 26, 2002, caused a copy of the foregoing to be placed in the interoffice mail addressed to Steve Sola, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, first class postage prepaid, to counsel for the Respondent, Robert G. Schmidt, CEO, Genesis 1:29 Corporation, 720 Southpoint Boulevard, Suite A, Petaluma, CA, 94954.



Carlene R. Thomas

Secretary