

following address: cormorants@fws.gov. The public may inspect comments during normal business hours in Room 4701, 4501 North Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT:

Brian Millsap, Chief, Division of Migratory Bird Management, or Shauna Hanisch (703) 358-1714.

SUPPLEMENTARY INFORMATION: On December 3, 2001, we published a notice of availability in the **Federal Register** (66 FR 60218) to announce that the DEIS on double-crested cormorant management was available for public comment. On December 19, 2001, we published a **Federal Register** notice of meetings and extension of the comment period (66 FR 65510) to announce the schedule of public hearings to invite further public participation in the DEIS review process.

The DEIS evaluates alternative strategies to reduce damages associated with double-crested cormorants in the continental United States. The DEIS is a comprehensive programmatic plan intended to guide and direct double-crested cormorant management activities. The DEIS examined six management alternatives for addressing conflicts with double-crested cormorants: (A) No action, (B) Nonlethal control, (C) Increased local damage control, (D) Public resource depredation order, (E) Regional population reduction, and (F) Regulated hunting. The proposed action/preferred alternative in the DEIS was alternative D, Public resource depredation order. This alternative entails: revising the existing aquaculture depredation order that applies to commercial freshwater aquaculture facilities and hatcheries to allow winter roost control; establishing a new depredation order to protect public resources from cormorant damages; and revising Director's Order 27 to allow lethal take of double-crested cormorants at public fish hatcheries. Alternative D is intended to enhance the ability of resource agencies to deal with cormorant damages in an effective and timely manner by giving them more regulatory flexibility. In the DEIS, alternatives were analyzed with regard to their potential impacts on double-crested cormorant populations, fish, other birds, vegetation, federally-listed threatened and endangered species, and socioeconomics.

On March 17, 2003 (68 FR 12653), we published a proposed rule in the **Federal Register** that would implement our preferred alternative. Because of the publication of the proposed rule, we have extended the comment period on the DEIS. We note that the proposed

rule presents the preferred alternative in a more detailed manner than the DEIS and advise the reader to refer to it. It is available at our Web site <http://migratorybirds.fws.gov>. The Service invites careful consideration by all parties, and welcomes serious scrutiny from those committed to the long-term conservation of migratory birds.

In order to be considered, electronic submission of comments must include your name and postal mailing address; we will not consider anonymous comments. All comments received, including names and addresses, will become part of the public record. Requests for such comments will be handled in accordance with the Freedom of Information Act and the Council on Environmental Quality's National Environmental Policy Act regulations [40 CFR 1506.6(f)]. Our practice is to make comments available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. If a respondent wishes us to withhold his/her name and/or address, this must be stated prominently at the beginning of the comment.

Dated: March 24, 2003.

Paul R. Schmidt,

Assistant Director, Migratory Birds and State Programs.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02-15]

Genesis 1:29 Corporation; Denial of Application

On December 13, 2001, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Genesis 1:29 Corporation (Respondent) of Petaluma, California, proposing to deny its application for DEA Certificate of Registration as a manufacturer of marijuana and tetrahydrocannabinol ("THC"), both Schedule I controlled substances. The statutory basis for the Order to Show Cause was Respondent's lack of state authorization to manufacture controlled substances in the State of California. 21 U.S.C. 824(a)(3). In addition, the Order to Show Cause alleged that Respondent's registration would be inconsistent with

the public interest, as the term is used in 21 U.S.C. 823(a) and 824(a)(4).

By letter dated January 9, 2002, the Respondent, acting *pro se* through its CEO Robert G. Schmidt (Mr. Schmidt), requested a hearing on the issues raised by the Order to Show Cause. The matter was then docketed before Administrative Law Judge Gail A. Randall (Judge Randall). In its request for hearing, Mr. Schmidt on behalf of the Respondent indicated that with respect to medical grade cannabis, the Respondent's interest in the instant proceeding was "to develop a federally approved and federally regulated dispensary model and research facility." The Respondent further indicated that its position on the pending DEA application was "flexible since there are no federally established guidelines for dispensing medical cannabis to patients other than for research purposes."

On January 25, 2002, Judge Randall issued an Order for Prehearing Statements. Following the filing of Prehearing Statements by the respective parties, on April 30, 2002, the Government filed its Request for Stay of Proceedings and Motion for Summary Judgment ("motion"). On May 23, 2002, Respondent filed its response to the Government's motion. On June 26, 2002, Judge Randall issued her Opinion and Recommended Ruling, granting the Government's motion, and recommending that Respondent's application for registration as a manufacturer be denied. Neither party filed exceptions to Judge Randall's Opinion and Recommended Ruling and on August 8, 2002, Judge Randall transmitted the record of these proceedings to the Deputy Administrator. The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth.

In its motion, the Government asserted that on November 11, 2001, DEA transmitted a series of written questions to the Respondent regarding its method of operations and intended customers. The Government attached to its motion a copy of the Respondent's November 26, 2001 response letter to DEA's questionnaire. In the attached response letter, Respondent indicated that the intended purpose of its bulk manufacture of marijuana was to "supply clinical cannabis to physician's patients operating within California state laws and guidelines established by California Public Health and Safety Code 11362.5 including 11362.7 and 11362.9 * * *" The letter further

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