

GENESIS 1:29
*A California Public Benefit
Non-Profit Corporation*

In the Matter of

Docket No. 02-15

GENESIS 1:29 CORPORATION

Respondent

RESPONDENT'S PREHEARING STATEMENT

Genesis 1:29 Corporation hereby submits its Prehearing Statement pursuant to the request made by presiding officer and Administrative Law Judge, Gail A. Randall on January 25, 2002. The Corporation submits that it is consistent with both public and private interest to register Genesis 1:29 Corporation (Hereinafter referred to as Respondent) as a manufacturer of herbal, and synthetic Cannabinoids, some of which are classified under Schedule I Controlled Substances named Tetrahydrocannabinols (THC), and particularly those cited in drug codes 7360 and 7370.

INTRODUCTION

Unlike several States of the Union in which laws regarding manufacturing and distribution of cannabis and cannabis related products have been initiated, recognized and authorized by state legislatures; Respondent operates in California, where state law

regarding the medical use of marihuana and/or cannabinoids was initiated not from state congress but rather from the People as a referendum for interest in public health.

This difference stems from the fact that previous legislative and administrative efforts to institute the plea for compassion for the seriously ill failed when the Governor of California vetoed, several times, over the period of years, any attempt to regulate and care for distressed populations like those of HIV/AIDS and cancer. The voters of the State responded by passing Health & Safety Code 11362.5 and later 11362.7 and left the Governor and State legislature unable to veto public initiatives. When needs demand attention and they are ignored, the system fails and The People safeguard their welfare. This is how medical cannabis prevailed and will continue to prevail in spite of law and/or abilities of Respondent.

It is from this environment that Respondent understood that the only way to provide an effective, safe, affordable and equally important — *legal* supply of medical grade cannabis was to have early and open communication and cooperation with not just State authorities but Federal ones as well. This is why the applicant has had filed Articles of Incorporation with the Secretary of State and filed to register with the Department of Justice every year. This also explains why Respondent, unlike many “Medical Cannabis Cooperatives,” conducts its specific purpose with a business license. Local law enforcement has continually patrolled and monitored Respondent’s facilities beginning as immediately as within 12 hours of passing of CH&SC 11362.5. When found in the

genuine service of the community, and serving the welfare of sick individuals, Respondent sees no reason to conduct service in a covert manner.

Respondent contends that not all marijuana or cannabis-related products have medicinal properties. Raw cannabis blossoms (Marijuana) have medical value only when their active substance meets quality, quantity, administration and delivery standards. If, for instance, cannabis blossoms were to contain mold, pesticides, herbicides, germicides, inorganic fertilizers, or any other synthetic/applied compounds—they would have no medicinal value. If, for instance, cannabis blossoms were free of all abovementioned adulterants but only contained minimal to trace amounts of active cannabinoids, say, less than 15% THC, and if the method of delivery is through smoke inhalation, results would be ineffective and therefore deemed not to have any medicinal value. Respondent asserts that past clinical trials have been conducted with poor clinical trials material and that any result indicating a lack of therapeutic value to cannabis smoking are invalid because of the strikingly poor quality of said clinical trials material. If one begins with poor clinical trials material, one will end up with poor results.

Cannabinoid pharmacology and its psychotomimetic qualities are well documented and have been known by medical professionals worldwide obtained through rigorous research and experimentation. Respondent has a key competence and knowledge of these qualities not only through experimental means but rather, and most importantly, through experiential ones. Prominent medical properties include but are not limited to: anti-emetic, anticonvulsant, bronchial-dilator, analgesic, appetite stimulator, anti-spasmodic,

antibacterial, anti-inflammatory, intra-ocular pressure reducer, anti-histaminic. These known properties are only a small number of the potential benefits of Cannabinoid therapies in the treatment of diseases of known and unknown etiology. To claim and then assert through force of law that cannabinoids have no medicinal value is an utter and vicious lie resulting in unjust laws that exacerbate the suffering of the seriously ill and conducts to acts against humanity.

BACKGROUND

Sydney Ford served as Respondent's president from date of incorporation, January 22, 1999, through his resignation in the evening of June 20, 2001 immediately after meeting with Diversion Investigator D/I and formally withdrawing all four (4) previously submitted applications.

During those thirty months two separate entities existed. The first, Genesis Pharms, a now inactive corporation was established exclusively for the purpose growing medical-grade cannabis. The other, Genesis 1:29 serves as a Non-profit entity primarily as a dispensary with little, if any, agricultural/manufacturing capability. As their name suggests, it makes sense that one would manufacture (Farm) and the other dispense. Both entities at that time sought registration with the Drug Enforcement Administration. Unfortunately, two of the four registrations submitted were not completed properly; one lacked the date of submittal and the other was missing the Applicant's contact phone number. The two uncompleted registrations did not meet requirements set by 21 CFR 1301.13 and Respondent re-submitted two applications under control numbers

D03233401H, D16011201H in the year 2001. Two were completed properly and filed for registration along with the appropriate fees. Shortly after re-submitting in May 1, 2001, Respondent's fees were collected but there was no news of Respondent's pending registration. This situation led the Respondent to meet with D/I Mark Iacangelo and field agent "Dan" at DEA's San Francisco Field Division Office.

During the visit with D/I Iacangelo on June 20, 2001, Mr. Iacangelo presented Mr. Ford with a letter indicating that the two pending registrations had not been approved and therefore he was not allowed to handle any controlled substance matter, including the handling of Marijuana, until properly registered. Mr. Ford refused to sign the letter worded by the San Francisco Field Division Office and hand wrote a formal withdrawal. Mr. Carlos A. Aguila (Chief Financial Officer-Genesis) and Mr. Robert G. Schmidt (Chief Executive Officer-Genesis) were not given a letter, nor did the letter that was prepared by the Field Division Office have their names addressed on it. They could not have been expected to sign any document not addressed specifically to them.

Furthermore, D/I Iacangelo informed that Respondent's web site stated that Respondent was registered as a research and manufacture facility with the DEA. Respondent claims that it was an unintentional embellishment done by the technical Webmaster (not residing in California and lacks close proximity), which meant to state that Respondent had *filed for registration*. Respondent corrected the error and modified the content within 24 hours of notice. Never did Respondent intend to misrepresent itself

as being duly registered with the DEA; It would not have brought good deed, nor made a significant difference in Respondent's public standing.

APPLICATION FOR REGISTRATION AT ISSUE

On September 11, 2001, Respondent mailed DEA Form 225, seeking registration for bulk manufacturing of Schedule I controlled substances (Codes 7360, 7370 *only*). The application was completed and signed by Respondent's C.F.O. – Carlos A. Aguila, knowing that Respondent's CEO's previous conviction could, perhaps, compromise being duly registered. Respondent claims that if the resignation of the C.E.O is necessary to allow proper registration, it would be done. The need for clinical-grade products containing cannabinoids is greater than any one organization can meet, let alone one man who has previously paid his debt to society in full.

Two months later, during the probation hearing of Steven Fisher, Respondent's C.F.O. also submitted to Mr. Larson, (DA Siskiyou County, Calif.) a copy of Channel 4 KRON-TV NEWS, San Francisco, video tape, as well as D/I Mark Iacangelo's business card, hand delivered so that they may contact each other.

All of Respondent's 'growers contracts' expire, at the end of a season, by midnight on December 31st, every year. Mr. Fisher's contract will not be renewed, since he had violated several criteria used to establish a contract set forth by county and state guidelines. Mr. Fisher failed to inform Respondent that he was involved in

probation matters prior to establishing and throughout his contract with Respondent. Mr. Fisher and his organization cultivated and harvested 184 plants, not all at once, of which one-third (1/3) of the crop—equaling to about 62 plants, belonged to Genesis 1:29. California Health & Safety Code 11362.5 as implemented by State Attorney Generals, Dan Lungren and Bill Lockyer has strong restrictions and offers weak defense for those in parole or probation matters.

Respondent's function with growers in the past years has been more like a mill than a manufacturer. Setting the quality standard, grading, drying, curing, for the grower. Respondent understands that in order to maintain absolute inventory and controls on controlled substance matter, chain of custody is critical. For this reason Respondent wishes to be registered as a manufacturer, so that issues in chain of custody, and quality can be improved further.

Under the "mill" model, it is very difficult to manage growers as 'regulated persons' where chain of custody is shared by two or more over vast geographies. Such is also the case with the logistics of (DEA Registered) The National Institute on Drug Abuse, where the, less than 5% active substance, 'clinical trials material' (CTM) leaves the University of Mississippi for packaging into tobacco-like cigarettes at the Research Triangle Institute in North Carolina. Then the product has to be transported through State boundaries to be dispensed to recipients throughout the Union. A careful study on the genetic origin of the plants used to produce the CTM resulted that the seeds originated from plants grown south of the Tropic of Capricorn. This further suggests that not only

are the plants not adapted to the environment they are grown for optimal clinical testing; it also suggests international transportation. If Respondent is registered as a bulk manufacturer, it would ensure that production and distribution would remain not just within the State but within county geographies and tolerances. Regulation by local City, State, and Federal Governments, at all levels of production, is plausible and desired by Respondent.

The sole issue of chain of custody in itself will ensure a more easily accessible, affordable, and superior product resolving many issues of safety, quality, quantity, and interstate commerce. Many would argue that, regulations only impede distribution, however, with localized, smaller production cooperatives this would not be the case. The already active and present Special Tax Stamp for producers of Marihuana (flower blossoms) could be applied to the land owner, grower, and dispensary, thus, effective in appropriating at all three levels of custody. Recognizing urgency, the Special Tax Stamp can be implemented today, being *prior* to and most importantly *independent* of re-scheduling efforts.

Granting Respondent registration will not only comply by setting a standard, but help enforce sections 304 and 505 of the Federal Food, Drug and Cosmetic Act dealing with purity standards for interstate commerce and provide substantial evidence that a new drug (Cannabis) has medical value and is safe for State, and interstate commerce. Whatever discrepancy that could exist between current standards and those proposed by Federal Agencies would be resolved much more quickly if respondent had proper

registration. Respondent would demand a time period, to prepare, and make whatever necessary changes to achieve full implementation and compliance.

Medical research involving Marihuana, since it is a natural herb, is inextricably linked to horticultural research. The quality of herbal extracts used for tonics or pharmaceutical purposes strictly relies on genetics and the horticultural techniques used to produce the herb. It is in public interest to provide subsidized farming, horticultural research and lower production costs by regulation. For instance, Respondent incurs over \$48,000 annually in insurance expense. This expense would be reduced to at most *half*; if Respondent was duly registered. Legitimacy and compassion provided by the Federal government would mean defraying medical costs and reducing crime. To do the opposite would allow foreign markets to advance ahead of the U.S. in medical, horticultural and industrial applications of Cannabis products. Registering Respondent would not amount to decriminalization, legalization, or reformation (re-scheduling), nonetheless, to many it would mean *restoration* and *hope*. It would be unwise to continue to criminalize, rather than regulate the herb; given the fact it provides relief to so many patients.

ISSUE

The issues at the hearing are:

1. Whether the Respondent has established by a preponderance of the evidence that it is in the interest to approve its pending application (DEA Form 225) for registration with DEA to manufacture marijuana and tetrahydrocannabinols (THC).

2. Whether the Respondent has established by a preponderance of the evidence that international treaty obligations permit Respondent to engage in the activity for which Respondent seeks a DEA registration.

STIPULATIONS

1. Although Marijuana and THC are Schedule I Controlled Substances, there is an unusual safety in their application with respect to potency vs. toxicity. Unlike Federally approved manufacturers of similar controlled substances, Genesis 1:29 Corporation has never experienced a single complication in its 5 years of service.

2. After extensive comparison of both synthetic and natural sources of federally approved cannabis related products, Genesis Corporation has determined that its product is by far superior in quality and safety than that used by the National Institute of Health and the Institute Of Medicine. Respondent's Patients are encouraged to use non-combustion therapies; vaporize (atomize) active substance without the need to combust materials such as cellulose which produce smoke. Those who do chose to smoke cannabis blossoms, do it out of *glass* instead of paper.

3. Federally approved cannabis blossoms contain a mean of approximately 8% active substance, the rest consisting of twigs, seeds, male flowers, and plant cellulose. It is sad to admit that Respondent's medicated cookies for patient ingestion contain higher grade active substance than does federally approved clinical trials material.

4. Genesis 1:29 serves public interest by offering state-of-the-art rehabilitation. It offers opportunities both in maintenance and detoxification treatments. Defraying the cost of traditional rehabilitation centers where Methadone (opiate narcotic), Diazepam (tranquilizers) and anti-depressant administration is a standard operating procedure, Respondent only utilizes Cannabinoids as medicine. In fact, some of the patients are utilizing cannabis to reduce their consumption of illegal drugs, prescribed ones, or in some cases legal drugs such as alcohol and tobacco. This approach called 'Harm Reduction' proves that Cannabinoid utilization serves as a powerful *antidote* to most nocuous drugs.

5. None of Respondent's work has ever received any funding or economic support other than limited contributions from The United Way, United Auto Workers, United Farm Workers, and the California State University. As a Non-profit and with limited support, Genesis cannot afford to conduct research amounting to \$300,000 in administering THC anally into rats (NIDA experiments), not to mention three (3) Million Dollars worth of *psychiatric* evaluations of cannabis patients performed by the University of California (another Federally approved agent) as established by Senate Bill 847 passed as CH&SC 11362.7 titled The Marijuana Research Act. Genesis Corporation witnesses results in willing, doctor-supervised human beings, not rats.

6. On September 11, 2001, Genesis 1:29 Corporation sought to be registered with DEA as a manufacturer of Marijuana (Drug code 7360) and THC (Drug Code 7370) filing DEA Form 225 signed by C.F.O. Carlos A. Aguila. The address listed was CEO's home, 133 Bond Ave. Petaluma, CA. 94954. Since then, the office and dispensary have moved to a business building in a commercial zone situated Between Nokia, and the Department of Motor Vehicles. Respondent's city business license has been re-issued for the third year since incorporation.

7. In the meeting with D/I Mark Iacangelo of June 20th 2001, Sydney Ford, then President of Genesis 1:29 and Genesis Pharms, withdrew all Applications for Registration prior to his resignation that evening. Mr. Iacangelo specializing in, and constituting a diversion officer had no authority to issue registration to Respondent. Administrative Law Judges, however, do have binding authority.

8. Mr. Schmidt's testimony at the probation hearing, *People vs. Fisher*, was at worst slightly inaccurate considering the triple negative questions posed by D.A. Mr. Larson. A careful analysis of his cross-examination reveals that he successfully blocked Robert G. Schmidt's testimony on several occasions (E.g. Page 81 lines 23-26, Page 82 lines 18-19, 28 and on Page 83 lines 2-8 of transcript of probation hearing *People vs. Fisher*, Case No. 99-1490). Respondent was placed under duress; felt upset and made said duress clear in line 8 on page 83.

9. Genesis 1:29 Corporation requires approved registration from the DEA prior to submitting a protocol since there *exists no license* or approval from the California Research Advisory Panel to conduct research using Schedule I Substances without proper DEA registration. Respondent's horticultural and medical research protocols are anxiously pending.

10. As with stipulation #9, The California Board of Pharmacy does not have a license to issue, nor are pharmacies equipped to distribute fresh herbs. Respondent could apply for exemption to the rule, however, without prior DEA registration, the board of Pharmacy will not issue a license.

11. In an attempt to maintain similar standards to those used in pharmacies, Respondent utilizes similar protocols. Patients call in their medication, prescriptions and records are verified, and patients are verified with State issued picture ID's by appointment only.

12. If Respondent cannot be approved for registration, its function as a dispensary would have to cease. This would leave over a thousand sick patients (in Sonoma County alone) who rely on their doctor and Genesis 1:29 for help, to seek help elsewhere. The People can be governed and regulated quite easily, but the *individual thinker*, particularly the *individual in need* cannot be governed as easily. When abandoned and left to help themselves, they govern themselves.

13. Respondent cares for the burden of at least 1000 sick individuals, State programs approved federally care for only a handful, and the Federal Compassionate IND/NIDA program cares for a total of seven individuals.

14. Co-signers of the Single Convention on Narcotics-- U.N. Headquarters N.Y., N.Y (1961) have already taken measure to implement legislation and regulation for medical marijuana. The UK, Germany, Holland, Belgium, Canada, Switzerland, Spain, Italy and other nations have, in essence, out-right violated this antiquated treaty enacted before our own Civil Rights Movement. How will those Nations assess or sanction individual rights and service to the public?

PRAYER

Benjamin Rush, a Medical Doctor and co-signer of The Declaration of Independence [fourth column from left – second signature from top – immediately above Benjamin Franklin’s signature] declared, “Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an undercover dictatorship...the Constitution of this Republic should make a special provision for medical freedom as well as religious freedom.”

WITNESSES

1. Robert G. Schmidt
Genesis 1:29 CEO
720 Southpoint Blvd Ste A
Petaluma, CA 94954
(707) 480-7712
2. Carlos A. Aguila

Genesis 1:29 CFO
720 Southpoint Blvd Ste A
Petaluma, CA 94954
(707) 480-7606

3. John D. Katz
Patient
Genesis 1:29
720 Southpoint Blvd Ste A
Petaluma CA 94954
(707) 837-9879

SUMMARY OF TESTIMONY

1. Robert G. Schmidt

CEO – Genesis 1:29 Corp.

Robert G. Schmidt will testify as to why it is in public interest to register Genesis. He will testify that there can be a 'regulated pilot' program that can work for the people and for the government. Mr. Schmidt will testify the he has never been an advocate of legalization or decriminalization but rather regulation. To regulate implies allowing a certain amount to flow for control and distribution. His will attest to the stipulations set forth in this document.

2. Carlos A. Aguila

CFO – Genesis 1:29 Corp.

Carlos A. Aguila will attest to the stipulations set forth. He will testify that it is in the public interest for City, State and in this particular case; Federal Government to take

part by duly registering Genesis 1:29 Corporation as a bulk manufacturer of drug codes 7360 and 7370.

3. John D. Katz

Patient

John D. Katz will testify and demonstrate how cannabis helps him medically.

DOCUMENTS

Respondent will offer the following Respondent Exhibits (RX) at the hearing:

1. Respondents Articles of Incorporation (3 pages).
2. Sonoma County Medical-Marihuana guidelines as set forth by District Attorney J. Michael Mullins May 7, 2001 (3 pages).
3. Typed testimony of John Dylan Katz, patient with Genesis 1:29 (1 page).
4. Research Mission Statement to apply to pending Research Protocol as per CIC and Clinical Research Commission guidelines on Clinical Investigation, 1999 (1 page).

5. Copy of the only letter passed to Respondent during the meeting with D/I Mark Iacangelo of June 20, 2001 (1 page).

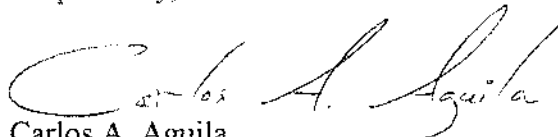
DESIRED LOCATION

Respondent declines to have the hearing in San Francisco, California. A Hearing in Washington, DC, is preferred.

BEST ESTIMATE OF TIME FOR PRESENTATION OF CASE

Respondent estimates that it will require one (1) day, presenting its case.

Respectfully,


Carlos A. Aguila
Chief Financial Officer
Genesis 1:29 Corporation

CERTIFICATE OF SERVICE

I certify that on March 28, 2002, I caused to be served upon the following individuals Respondent's (Genesis 1:29) Prehearing Statement to the following addresses in the manner indicated:

Gail Randall
Administrative Law Judge
Drug Enforcement Administration
Arlington, VA 22202
(By First Class Mail)

Hearing Clerk
Office of Administrative Law Judges
Drug Enforcement Administration
Washington, D.C. 20537
(By First Class Mail)

Carlos A. Aquila

NAME

MARCH 28, 2002

DATE