Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537; Attention: Drug Operations Section, Domestic Drug Unit (ODOD) and must be filed no later than June 9, 2003.

Dated: March 21, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–8583 Filed 4–8–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substances in Schedule I or II and prior to issuing a registration under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on February 14, 2003, Boehringer Ingelheim Chemicals, Inc. 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import Phenylacetone for the bulk manufacture of amphetamine.

Any manufacturer holding, or apply for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Drug Operations Section, Domestic Drug Unit (ODOD), and must be filed no later than May 9, 2003.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), (f). As noted as a previous notice at 40 FR 43745–46 (Sepember 23, 1975), all applicants for registration to import basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.452(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: March 21, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–8585 Filed 4–8–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 5, 2001, and published in the **Federal Register** on October 17, 2001, (66 FR 52780), Boehringer Ingelheim Chemicals, Inc., 2820 N. Normandy Drive, Petersburg, VA 23805, made application by renewal to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic class of controlled substances listed below:

Drug	Schedule
Methylphenidate (1724)	II

The firm plans to manufacture the listed controlled substance for formulation into finished pharmaceuticals.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of, Boehringer Ingelheim Chemicals, Inc., to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Boehringer Ingelheim Chemicals, Inc. to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: March 21, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–8587 Filed 4–8–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 01–1]

The Church of the Living Tree; Denial of Application

On November 4, 1999, and pursuant to 21 U.S.C. 823(a), the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to the Church of the Living Tree (Respondent) of Leggett, California, proposing to deny its application for DEA Certificate of Registration as a manufacturer of marijuana, a Schedule I controlled substance. The Order to Show Cause alleged that the pending application should be denied because the Respondent's proposed manufacture and distribution of marijuana for human consumption was a purpose not in conformity with the provisions of the Controlled Substances Act, under 21 U.S.C., section 2 812(b)(1), 822(b), 823(f)(4), and 841(a)(1).

By letter dated November 26, 1999, the Respondent, through its trustee John Stahl (Mr. Stahl), timely filed a request for a hearing on the issues raised by the Order to Show Cause, stating, in part, that Respondent sought ''* * * to cultivate cannabis sativa for purposes which are allowable under California Law, and to process the remaining stalk into pulp for our paper mill.'' Through inadvertence, this request was not docketed for a possible hearing. As a result, the then-Deputy Administrator of the DEA issued a final order finding that Respondent had not responded to the Order to Show Cause and denying

Respondent's application. 65 FR 50,567 (August 3, 2000). However, by error, and the agency subsequently rescinded the prior final order by order dated November 21, 2000. 65 FR 75958 (2000). The matter was then docketed before Administrative Law Judge Mary Ellen Bittner (Judge Bittner).

On October 23, 2000, the Government filed a Motion for Summary Disposition, reiterating the allegations contained in the Order to Show Cause and further alleging, in part, that the manufacture of marijuana for human consumption is a purpose not in conformity with the Controlled Substance Act. The Government further argued that DEA rejected a previous petition to reschedule marijuana when it found that the drug has no currently accepted medical use. Marijuana Scheduling Petition; Denial of Petition; Remand, 59 FR 10,499, 10,507 (1992). The Government added that because the Respondent's previous DEA application for registration as a marijuana manufacturer was denied, the Respondent is now precluded from re-litigating the matter in its renewed effort to obtain a similar registration under the doctrine of res judicata. Robert A. Leslie, M.D., 64 FR 25,908 (1999); Robert M. Golden, M.D., 63 FR 38,669 (1998).

On November 1, and December 1, 2000, the Respondent filed its Response to Motion for Summary Disposition and Further Response to Motion for Summary Disposition respectively. In its submissions, the Respondent argued in essence that it ''* * * intended to cultivate medical marijuana as a cooperative farm of * * * patients qualifying under the terms of the Compassionate Use Act of 1996 (the Compassionate Use Act).'' As noted in a previous DEA final order, effective November 6, 1996, voters in California adopted the Compassionate Use Act, which provides that persons may grow or posses marijuana ''upon the written or oral recommendation or approval of a physician.'' Cal. Health & Safety Code section 11362.5 Marion ''Molly'' Fry, M.D., 67 FR 78015, 78017 (2002). The Respondent further argued in relevant part that California's marijuana law should be given deference by the Federal Government, and the Government's motion for summary disposition rejected, since there remained a fundamental question for resolution by the instant proceedings: whether Respondent's application should denied despite its engaging in activities that are now sanctioned under California state law (*i.e.,* cultivation of marijuana for human consumption).

On April 17, 2001, Judge Bittner issued her Opinion and Recommended Decision, granting the Government's Motion for Summary Disposition and recommending that Respondent's application for DEA registration be denied. Neither party filed exceptions to Judge Bittner's recommended ruling, and on June 12, 2001, the record was transmitted to the Deputy Administrator for his final decision. 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. The Deputy Administrator adopts the Opinion and Recommended Decision of the Administrative Law Judge, and finds as follows:

On January 21, 1997, the Respondent submitted a prior application to DEA as a manufacturer of marijuana for human consumption. The Respondent proposed to rent space on its property to individuals qualifying under California State law as medical marijuana patients, who would then cultivate marijuana for personal consumption, leaving the mature stalks for Respondent to process into paper. On April 17, 1998, DEA issued an Order to Show Cause seeking to deny the application on grounds that the Respondent was not authorized by the State of California to cultivate marijuana. The Respondent filed a timely request for hearing, and the matter was docketed before Judge Bittner as Church of the Living Tree, DEA Docket No. 98–26 (Church of the Living Tree 1). On May 21, 1998, the Government filed a motion summary disposition, alleging inter alia, that California law did not permit cultivation or harvesting of marijuana, and as a result of Respondent's lack of state authorization to manufacture marijuana for non-human consumption, DEA could not grant its application for registration as a matter of law.

In response to the Government's motion, and with arguments similar in scope to its present request for registration, the Respondent asserted in relevant part that the purpose of its application as a bulk manufacturer of medical marijuana was decidedly ''for Human Consumption'' and in compliance with California law. On July 31, 1998, Judge Bittner issued a recommended decision, in which she granted the Government's motion for summary disposition and recommended that the Respondent's application be denied.

In his final order published as Church of the Living Tree, 63 FR 69,674 (1998), the then-Deputy Administrator found that from a reading of the Respondent's marijuana manufacturing proposal, ''* * * it is clear that Respondent will be renting space on its property to others, but [Respondent] will not be the one manufacturing marijuana. Therefore * * * since Respondent will not be manufacturing marijuana nor is it proposing to manufacture marijuana, its application to be a manufacturer of marijuana must be denied.'' 21 U.S.C. 822(a) and 823(a). The then-Deputy Administrator added, ''* * * if Respondent's application is for registration to manufacture marijuana for non-human consumption, then it would have to be denied because California does not allow the cultivation of marijuana for non-human consumption.''

As noted above, on June 18, 1998, the Respondent submitted its most recent application for DEA registration as a manufacturer of marijuana in the category of bulk synthesizer-extractor. In support of the application, the Respondent asserted that its intentions are to cultivate medical marijuana as a cooperative farm of California patients qualifying under the terms of the Compassionate Use Act of 1996. The Respondent further contends that Art.I, sec. 8 and the Tenth Amendment to the United States Constitution provides the right to States to regulate their internal affairs. Therefore Respondent argues, since the proposes uses for its registration complies with California law, Respondent's pending application should be granted.

In the April 17, 2001, Opinion and Recommended Decision, Judge Bittner found that while Respondent seeks registration as a bulk synthesizer-extractor of marijuana, and although the Respondent is apparently willing to modify its application to the ''non-human consumption'' category, the Respondent's application cannot be granted under either category. The Deputy Administrator concurs with this finding. DEA concluded in Church of the Living Tree I that if Respondent rents out space to medical marijuana patients to cultivate marijuana, Respondent will be the entity doing the cultivation and therefore cannot be registered as a bulk synthesizer-extractor of marijuana. With respect to its instant application, the Respondent has not indicated that it seeks registration for purposes of growing marijuana for non-human consumption. In any event, there remains a lack of evidence before the Deputy Administrator that California law provides for the cultivation of marijuana for non-human consumption.

The Respondent has once again submitted an application for registration

as a manufacture of marijuana for human consumption. Such use of a DEA registration is not in conformity with provisions of the Controlled Substances Act. As noted above marijuana is listed in Schedule I of the Controlled Substances Act (CSA). 21 U.S.C. 812(c); 21 CFR 1303.11. The CSA defines Schedule I controlled substances as those drugs or other substances that have ''a high potential for abuse,'' ''no current accepted medical use in treatment in the United States,'' and ''a lack of accepted safety for use * * * under medical supervision.'' Also, every drug listed in Schedule I of the CSA lacks approval for marketing under the Federal Food Drug and Cosmetic Act (FDCA). Therefore, the Food and Drug Administration (FDA) has not approved marijuana for marketing as a drug.

The deleterious effects of marijuana use have been outlined extensively in previous DEA final orders and will not be repeated at length here. Marion ''Molly'' Fry, M.D. at 79015. *See also,* 66 FR 20038 (2001) 57 FR 10499 (1992). However, it bears mentioning again that the numerous significant short-term side effects and long term risks linked to smoking marijuana, include damage to brain cells; lung problems such as bronchitis and emphysema; a weakening of the body's antibacterial defenses in the lungs; the lowering of blood pressure; trouble with thinking and concentration; fatigue; sleepiness and the impairment of motors skills. *Id.*

Marijuana was placed in Schedule I for the same fundamental reason that it has never been approved for sale by the FDA; there have never been any sound scientific studies which demonstrate that marijuana can be used safely and effectively as medicine. See 66 FR 20038 (April 18, 2001) (DEA final order denying petition to initiate proceedings to reschedule marijuana). The Supreme Court recently explained the legal significance of marijuana's placement in Schedule I of the CSA:

> Whereas some other drugs (those in Schedules II through V) can be dispensed and prescribed for medical use, *see* 21 U.S.C. 829, the same is not true for marijuana. Indeed, the purposes of the Controlled Substances Act, marijuana has ''no currently accepted medical use'' at all.

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 482, 491 (2001).

Federal law prohibits human consumption of marijuana outside of FDS-approved, DEA registered research. *Id.* at 490 (''For marijuana (and other drugs that have been classified as 'schedule I' controlled substances), there is but one express exception, and it is available only for Government approved research projects, section 823(f).''). *Id.* at 495 n.7.

In light of the Respondent's pending DEA application which by law cannot be granted, the Deputy Administrator concurs with Judge Bittner that there are no material disputed facts in this matter. Accordingly, the Government's motion for summary disposition was properly entertained and granted. 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. The rationale is that Congress does not intend administrative agencies to perform meaningless tasks. 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). For the above-stated reasons, the application of Respondent must be denied.

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 a DEA Certificate of Registration submitted by the Church of the Living Tree, be, and it hereby is, denied. This order is effective April 9, 2003.

Dated: March 26, 2003.

John B. Brown, III,

Deputy Administrator.

[FR Doc. 03–8590 Filed 4–8–03; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on November 13, 2002, Dade Behring Inc., Route 896 Corporate Boulevard, Building 100, Attn: RA/QA, P.O. Box 6101, Newark, Delaware, 19714, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Ecogonine (9180)	II
Morphine (9300)	II

The firm plans to produce bulk products used for the manufacture or reagents and drug calibrator/controls, DEA exempt products.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Drug Operations Section, Domestic Drug Unit (ODOD) and must be filed no later than 60 days from publication.

Dated: March 21, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–8581 Filed 4–8–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on August 20, 2002, Syva Company, Dade Behring Inc., Regulatory Affairs Department E1–310, 20400 Mariana Avenue, Cupertino, California, 95014, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Ecogonine (9180)	II
Morphine (9300)	II

The firm plans to produce bulk products used for the manufacture of reagents and drug calibrator/controls, DEA exempt products.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug