

Betty H. Galloway

From: "Gust, Steve (NIH/NIDA)" <sgust@nida.nih.gov>
 To: "Mahmoud A. ElSohly Ph.D." <elimaee@watervalley.net>
 Cc: "Singh, Hari (NIH/NIDA)" <hsingh1@nida.nih.gov>
 Sent: Monday, September 08, 2003 12:09 PM
 Attach: DEA RESPONSE.doc
 Subject: FW: DEA Response, Draft #2

thank you. i have made a few suggested changes. please take a look. i also added our sentence that you should feel free to change. it is the one about the lack of complaints. it would be good to have something in the statement about overall acceptability of the marijuana to the researchers.

—Original Message—

From: Mahmoud A. ElSohly Ph.D. [mailto:elimaee@watervalley.net]
 Sent: Monday, September 01, 2003 5:03 PM
 To: Walt Chambliss; Walt Chambliss; Gust, Steve (NIH/NIDA); Steve Gust; Larry Walker; Singh, Hari (NIH/NIDA)
 Subject: DEA Response, Draft #2

Attached is a second draft of our proposed response to the University of Massachusetts-Amherst's application for a manufacturer's license to manufacture (cultivate) marijuana and tetrahydrocannabinols

Hari and Steve, please note that this revised draft will have no graphs or tables attached

Larry and Walt, i have incorporated your suggestions and, in addition, i have inserted the fact that the contract with NIDA is awarded through an open competitive bidding process and that the University of Massachusetts-Amherst can file a competitive bid for the next contract which is up for renewal in 2004.

I look forward to hearing from all of you before I finalize the response..

MAF

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Bettye H. Galloway

From: "Mahmoud A. ElSohly Ph.D." <elima@water valley.net>
To: "Steve Gust" <sgust@nida.nih.gov>; "Hari Singh" <hsingh1@nida.nih.gov>; "Wait Chambliss" <wchambli@sunset.backbone.olemiss.edu>; "Wait Chambliss" <chamblissw@aol.com>; "Larry Walker" <lwalker@olemiss.edu>
Sent: Friday, August 29, 2003 7:06 PM
Attach: DEA RESPONSE.doc
Subject: RESPONSE TO FEDERAL REGISTER NOTICE

Attached is a draft response to the Federal Register notice regarding the University of Massachusetts-Amherst application for DEA registration to manufacture marijuana and tetrahydrocannabinols for distribution to researchers.

Please go over this draft and provide me with any comments you might have to finalize the response. I understand, Dr. Gust and Dr. Singh, that I might have information there that NIDA would not want me to include, and I'll certainly remove it if that is the case, and there might be additional information you might want to have included, and I'll be glad to add it.

Larry and Wait, I am not sure whether or not this should go through Dr. Clark's office or the University Attorney, but I'll leave this up to you to give me the final feedback.

I hope to receive your response sometime early next week so that I may be able to submit the final draft to DEA before my trip to Germany leaving on the 9th of September.

Please note that this e-mail is coming from my private lab since that is where I am right now!

Have a good, long weekend.

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8/29/2003

September 1, 2003

DRAFT #2

Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
US Department of Justice
Washington, DC 20537

ATTN: Federal Register Representative (CDD)

The Honorable Deputy Assistant Administrator

This is in response to the Federal Register Notice dated July 24, 2003 (FR/Vol 68, No 142/Thursday, July 25, 2003 (Notices)) relative to "Manufacture of Controlled Substances; Notice of Application."

In the above-referenced notice it is stated that "the University of Massachusetts-Amherst plans to bulk manufacture (cultivate) marijuana and tetrahydrocannabinols for distribution to approved researchers."

As a present registrant with the DEA to manufacture such substances (DEA Registrations #RN0281369 and RN0253574), I hereby provide comments and objections to the approval of the University of Massachusetts application.

The University of Mississippi, National Center for Natural Products Research, has two registrations with the DEA to manufacture (cultivate) marijuana and tetrahydrocannabinols. One of these registrations (#RN0281369) is specific to manufacturing these materials for the National Institute on Drug Abuse (NIDA), the federal agency in charge of overseeing research activities with marijuana and tetrahydrocannabinols as Schedule I substances.

Under NIDA's registration, materials are made available to researchers, with proper registration with the DEA and FDA, to carry out their research activities. Those researchers are required to provide proposals and protocols for their studies to NIDA for review. Those researchers with projects approved and funded by NIH (including NIDA) receive marijuana at no cost to them or their institutions. Those researchers with projects that do not meet the are not funded by NIH but have received scientific approval criteria by NIDA receive marijuana at the cost of production. Therefore, approved researchers already have access to research materials, and approval of another registrant is unnecessary.

The University of Mississippi has been under contract with NIDA, through a competitive bidding process where the contract is re-advertised every three to five years, since the late 1960s to grow, harvest, and analyze marijuana for research, and NIDA has been providing marijuana from Mississippi to researchers from that time until today. Under the current contract with NIDA, we at the University of Mississippi (the primary contractor) have in stock an ample supply of marijuana (hundreds of pounds) at different potencies ranging from less than 1% THC content to 10% THC content and greater. These materials are enough both qualitatively and quantitatively to satisfy any possible needs of the research community. In addition, through our subcontractor (Research Triangle Institute—RTI), we have thousands of marijuana cigarettes manufactured under cGMP for use in research projects under the NIDA program. Again, these cigarettes are provided to researchers at no charge if their project is approved by NIH or NIDA or at cost if the project is ~~not approved by NIDA~~ funded by other sources and the investigator(s) wish to pursue the project. The potency of the cigarettes available in the program ranges from 0% THC (placebo) to over 6% THC, and we have prepared a special batch at 8% THC. There is absolutely no shortage of material for use by approved investigators at any of the THC levels (low, medium, and high potency).

Since the inception of the program and implementation of the process of making marijuana and marijuana cigarettes available for research, the objective was to make cigarettes at potencies comparable to that of average marijuana potency being used by the general population. A potency monitoring program was put in place where samples of confiscated marijuana from around the country are analyzed for their THC content, and the data generated are used by NIDA and DEA for policy-making decisions. In fulfillment of the requirements of this program, the University of Mississippi has received and analyzed over 49,000 confiscated marijuana samples over the last 35 years.

The University of Mississippi has been responsive to the changing needs of the research community. For years, the THC level of confiscated marijuana was consistently below 4% and, therefore, marijuana cigarettes were manufactured for NIDA with potencies ranging from 1.5% to 4% to allow for dose ranging studies.

Over the last few years, we have noticed a gradual rise in THC content in excess of 4%. We have responded by making higher potency marijuana available for investigators. Our current inventory has over 50,000 cigarettes with potencies above 6%. In addition, our bulk marijuana inventory has hundreds of pounds of high potency material ready to be processed into cigarettes if need be.

For your further information, in the early stages of the program and up until the last four years, the process of manufacturing the cigarettes in bulk was such that other plant parts (other than leaves), such as small seeds and small stem particles, occasionally made their way into the cigarettes. ~~Proponents of marijuana legalization criticized the NIDA-provided cigarettes for the presence of this material as well as for the potency of THC. These criticisms are largely unfounded and arise more from the resentment of federal enforcement laws than from actual problems with the materials available. As mentioned above, we have addressed the issue of potency even though there are few investigators~~

using the high-potency cigarettes at this time since most research subjects are not capable of tolerating the high-potency material. Although we do not believe the occasional presence of small seeds and stem particles in the NIDA cigarettes was a significant issue, we responded to the issue by installing custom-manufactured de-seeding equipment that rids the plant material of any seeds or small stems prior to the manufacturing of the cigarettes. We are currently providing our subcontractor with plant material that has absolutely no seeds or heavy stem particles. It is important to note that we have not received any formal complaints from researchers about the adequacy of the marijuana for research purposes.

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country

In addition to the above-described NIDA program and the availability of materials through that program, we at the University of Mississippi have a separate DEA registration (#R-0253574) to manufacture (cultivate) marijuana and manufacture tetrahydrocannabinols. Materials could be made available to researchers outside the NIDA program if they are properly registered with the DEA and for some reason do not wish to receive or are not qualified to receive materials under the NIDA program. We are prepared to meet any need, qualitatively and quantitatively, in this area.



Therefore, we strongly feel that it is absolutely unnecessary to approve another manufacturer's registration to manufacture (cultivate) marijuana and tetrahydrocannabinols for distribution to approved researchers. Approval of the University of Massachusetts-Amherst would result in a duplication of existing resources without any foreseeable benefits.

Should the University of Massachusetts-Amherst feel that they have the capability, resources, and know-how to manufacture (cultivate) marijuana and tetrahydrocannabinols to distribute to researchers, perhaps they should compete for the next cycle of renewal of the current NIDA contract. This contract is up for renewal through an open competitive bidding process sometime in 2004.

Consequently, for all of the reasons cited above, we object to the issuance of a manufacturer's registration to the University of Massachusetts-Amherst.

We shall be glad to answer any questions or to provide specific data related to our response.

Sincerely,

Mahmoud A. ElSohty, Ph.D.
Research Professor