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NATIONAL CENTER FOR NATURAL PRODUCTS RESEARCH

a division of The Research Institute of Pharmaceutical Sciences

September 9, 2003

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

ATTN: Federal Register Representative (CCD)

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-Amherst 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 with projects approved and funded by NIH (including NIDA) receive marijuana at no cost to them or their institutions. Those researchers with projects that are

not funded by NIH but have received scientific approval 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 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. 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.

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.

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,

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Research Professor and
Director of the NIDA Marijuana Project