

Laboratories for Natural Products  
Medicinal and Aromatic Plants

June 2, 2003

Mr. Frank Sapienza  
Chief, Drug & Chemical Evaluation Section  
Drug Enforcement Administration  
U.S. Department of Justice  
Washington, D.C. 20537

RE: Response to your letter of March 4, 2003.

Dear Mr. Sapienza:

This letter is in response to your request for more information regarding my manufacturing application for marijuana. During the visit of DEA investigators (Mr. Simes and Mr. Levin) to the University, several items were discussed, primarily focusing on the need for an alternative source of plant material to that grown at the University of Mississippi under contract to the National Institute on Drug Abuse (NIDA). A second source of plant material is needed to facilitate privately-funded, FDA-approved research into medical uses of marijuana, ensuring a choice of sources and an adequate supply of quality, research-grade marijuana for medicinal applications. Ultimate testing of marijuana for medicinal use will undoubtedly cost several millions of dollars, an expense that private drug companies will be hesitant to invest without assurances of being able to evaluate various plant sources.

While I recognize that the primary researchers now receiving plant material may openly state to you that they are satisfied with the current source, I am sure you appreciate that in private conversations these same researchers indicate a fear of having the current supply eliminated if they complain about the available source material. This of course presents a dilemma that is difficult to recognize or solve, especially when no alternative to the current supply of plant material is available. Establishing a second source will promote more openness and higher quality material for testing the efficacy of marijuana as a medicine, something I know that you are anxious to determine.

To illustrate the problem of quality, I have enclosed copies of two documents for your review, both of which I know you are familiar (the letter you received from Dr. Russo and an article from the San Mateo County Times quoting Dr. Israelski, Director of Medical Research at the San Mateo Medical Center in California). In my professional opinion, the interests of DEA in research on medical marijuana would be best served by a second controlled source of plant material for that research. We have been working on the growth and cultivation of medicinal plants for over 20 years and have established national and international reputations for the quality of our work in medicinal plant research. We recognize the need for security and are prepared to meet those requirements. The University of Massachusetts fully supports our efforts in this direction.

I trust the above fully explains our position and indicates that we are anxious to move forward. If I can offer any additional information, please do not hesitate to contact me. Thank you for your interest in our program.

Sincerely yours,

Lyle E. Craker  
Professor

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