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September 9, 2005

Mr. Joel Egertson
Assistant Secretary for Health
Office of the Secretary, Office of Public Health and Science
US Department of Health and Science
Hubert H. Humphrey Building, Room 736-E
200 Independence Ave. SW
Washington, DC, 200201

Dear Mr. Egertson:

In response to document received August 15th 2005, Chemic Laboratories is certainly disappointed that the review committee has seen fit not to recommend the vaporizer study (as defined in Study Protocol issued on January 29, 2004) be completed. Thus purchase and importation of research grade Marijuana is unattainable. I would like to take the opportunity to respond to several of the comments made by the reviewers, as I believe there may be some confusion and/or misunderstanding on specific points described within the protocol. Please note, several of these points (and/or paraphrased statements thereof) have been documented in correspondence forwarded to the Study Sponsor (MAPS) for the sake of file completion.

The reviewers indicated HHS's focus is the support of "clinically" meaningful research. Chemic has been quite clear that the study was not a clinical investigation but a GLP study to support the assessment of the vaporizer device. Secondly the comparison of NIDA versus Dutch Medicinal marijuana is commented to be of little scientific value. Chemic's objective was to evaluate the differing vaporization efficiencies of CBD and CBN. Chemic's current understanding is that the only source of marijuana of varying concentrations is that of the Dutch Medical Office. It is unclear to me how this is "of little scientific value".

The reviewers indicate the aims of the project appear to be works necessary to be conducted as part of a GLP clinical study, but appear that some of the work had been previously completed. Chemic did complete several pilot investigations with the volcano. All these previous studies were proof of concept studies supporting the development of a protocolled cGMP study. It appears the reviewers have not recognized this point.

There is some confusion over the analytical techniques. It was intended that the cannabinoids would be assayed by HPLC-DAD-MS. That diode array detection would be used for quantitation and the mass spectrometer would be used for qualitative identification. Also The GC-MS analysis was to be used for the analysis of pyrolysis products, not cannabinoids as referenced by the reviewers.

Lastly, the use of caffeine as an internal standard (although not of a similar compound structure as noted by the reviewers) has been demonstrated during the pilot investigations to have very similar extraction efficiency and instrument response factor. Caffeine is also recommended by the instrument manufacture (Agilent Technologies) as a suitable reference material for monitoring the system suitability of the instrumental analysis. It is for these three reasons Caffeine was chosen as an internal standard.

In conclusion, again let me state my disappointment in the lack of recommendation to allow the study to move forward. However, Chemic and the study sponsor (MAPS) appreciate the time and effort the reviewing body and you have expended in considering the proposed vaporizer study.

Sincerely,
CHEMIC LABORATORIES, INC.

Joseph P. St. Laurent
President, CSO

CC: Rick Doblin Ph.D., MAPS