DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

JAN 23 2009

Mr. Joseph St. Laurent
President, CSO Chemic Laboratories, Inc.
480 Neponset Street-Bldg. 7
Canton, MA 02021

Dear Mr. St. Laurent:

The Department of Health and Human Services appreciates your study proposal on the Evaluation of Volcano Vaporizer for the efficient emission of THC, CBD, and CBN and the significant reduction and/or elimination of total particulate matter (TPM) and Tar components. This proposal is of considerable interest to the department.

However, the committee has a concern which must be addressed before you receive approval for medical marijuana. The committee requests validation data for quantification of Δ9-tetrahydrocannabinol (THC), cannabidiol (CBD) and cannabinol (CBN) to support your scientific measurements. In your response please ensure data is labeled and described so the committee can accurately evaluate your plan for measurement. To assist in your response, I will enclose a list of questions which are a part, but not inclusive of method validation.

Once you provide this information the committee will evaluate your responses and provide a timely decision. I appreciate your understanding and cooperation during this process. Please contact me if you need additional information or have questions.

Sincerely,

Gregory T. Goldstein
Senior Public Health Advisor

Enclosure

The questions listed below are guidelines for necessary validation data; however this is not inclusive of all aspects of method validation.

The Laboratory indicated that deuterated THC was used as the internal standard for all three analytes, but were response factors individually determined from CBD and CBN standards to determine the concentrations of these analytes? What does the laboratory mean that relative response factors were estimated to be equivalent? Where are the data indicating that all three compounds had similar response factors?

Why were total ion chromatograms (TIC) used for identification of cannabinoid compounds rather than selected ion monitoring for compound specific ions? Why was the power of the mass spectrometry data not used (fragmentor turned off) to improve selectivity of compound identification?

What are retention time criteria? What are appropriate chromatography criteria including peak shape, peak resolution, S/N?

Are the concentrations of each calibrator individually determined against the entire curve? What is the acceptable concentration range? Are there procedures for eliminating specific calibrators if they do not meet the criteria? How many calibrators can be dropped from the curve? Are calibrators prepared at the same time as samples?

Where are quality control samples? Are quality controls (preferably 3 across the linear dynamic range of the curve) prepared independently and assessed at the beginning and end of the batch or more frequently?

How was selectivity and potential interferences evaluated? How were other endogenous compounds within Cannabis sativa plant material evaluated to assure lack of interference? Were cannabigerol, cannabichromene for example, evaluated for interference with target compounds?