9. Summary of Safety and Effectiveness

The sponsor Technical Chemicals and Products Inc. (3340 S.W. 15th Street, Pompano Beach, Florida, 33069) has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Cannabinoids and their metabolites in a screening format. This summary was originally written in May of 1995 and has been updated as of March, 1996

The Trade name of the device is One Step™ Urine Drug of Abuse Cannabinoid Test (*THC*) having a designated common name of Cannabinoid Test System and a classification as a class II device per 21 CFR 862.3870. This device is intended for medical/forensic screening of urine.

TCPI's One Step™ Urine Drug of Abuse Cannabinoids test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 50 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

The sponsor subjected the final product to both in house testing of 249 individual urine samples using both the Sigma SIA™ THC, Syva Emit and GC/MS against the new product. The calculated sensitivity and specificity both equal 1.00 with the accuracy of 100%. Subsequently the device was subjected to a broader clinical trial in a NIDA certified laboratory where the calculated sensitivity equaled 1.00, the specificity equaled 0.9935 and the calculated accuracy equaled 99.67% when compared to the gold standard of GC/MS. Statistical comparisons of all possible combinations of reference methods to the experimental new device failed to identify any significant difference.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, Exec Vice President, Technical Chemicals & Products Inc. at 954-979-0400 or by fax at 954-979-0009.