MEDTOX®
LABORATORIES, INC.

May 29, 2001

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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

To Whom It May Concern:

The following comments are in reference to the Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA, released for comment on March 1,2001. These comments are being submitted on behalf of MEDTOX Scientific, Inc., MEDTOX Laboratories, Inc., and MEDTOX Diagnostics, Inc.

MEDTOX commends the FDA for its effort in gathering additional information from stakeholders in order to effectively implement its new responsibilities regarding CLIA waiver test decisions.

As background MEDTOX Scientific, Inc., headquartered in St Paul, Minnesota, is a provider of high quality laboratory testing and on-site/ point-of-care testing devices. MEDTOX Diagnostics, Inc., FDA establishment registration number 1050155, develops and manufactures diagnostic devices for quick and economical on-site / point-of-care analysis for drugs of abuse, therapeutic drugs, and agricultural toxins. MEDTOX Laboratories, Inc. is a SAMHSA certified, College of American Pathologist, Forensic Urine Drug Testing accredited laboratory providing employment drug testing and is a high complexity CLIA accredited, College of American Pathologist, Laboratory Accreditation Program accredited laboratory providing esoteric toxicology and occupational health testing services to companies, hospitals, and laboratories nationwide. MEDTOX Laboratories, Inc. maintains all applicable federal, state, and local licenses and permits for both forensic toxicology and clinical laboratory testing. As a provider of laboratory testing services and a manufacturer of on-site / point-of-care devices, MEDTOX is truly a stakeholder and is grateful for the opportunity to comment. Our comments are as follows:

- MEDTOX agrees that waived test systems must be simple, easy to use laboratory tests with an insignificant risk of erroneous results. MEDTOX agrees with the characteristics of "simple" as described in the Guidance and the need for hazard analysis and device quality control. We believe

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that single-use devices should have an on-board reactive control that ensures the validity of the test result and alerts the user to an error. The need for external quality control routinely should not be necessary. We refer to the NCCLS EP 18-P Quality Management for Unit-Use Testing; Proposed Guideline.

- MEDTOX agrees that accuracy should be demonstrated using untrained and professional users, however we request clarification and additional guidance for qualitative devices that measure multiple analytes on a single device. An example is a 5, 7, or 9 panel drug-screening device. We suggest the number of untrained users remain at 300 and they be permitted to perform more than one observation. We also suggest that multi-constituent testing material be permitted to minimize the number of specimens needed when multiple analytes at multiple target concentrations are to be tested. We also request clarification of the statistical method sited to analyze the odds ratio for the untrained user versus the trained user in the "Performance Targets for Qualitative tests".
- MEDTOX believes that manufacturers should provide technical support and customer service for their products, and develop training materials to ensure the users are performing the tests properly.
- MEDTOX disagrees in general with the section on Voluntary Safeguards for Waived Tests. Manufacturers currently have mandatory programs that address problems, complaints and corrective action without using MedWatch. Surveillance should not be the responsibility of the manufacturers. If quality problems exist in certificate of waiver (COW) facilities, it is HCFA's responsibility to inspect and ensure compliance or require participation in a proficiency program, however this is inconsistent with the CLIA standards for COW facilities. We suggest HCFA develop a program to ensure quality of the tests performed in COW facilities, a program that is consistent and not does vary with the manufacturer.

This concludes our comments. We appreciate the opportunity to submit comments for consideration. If any additional information or clarification is required, please contact me at spuskas@medtox.com or 651-636-7466.

Sincerely,

Susan Puskas BS MT(ASCP) SC
Director Quality and Regulatory Compliance
MEDTOX Laboratories, Inc.

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