April 18, 2006

Laboratory 0485
Responsible Person
Sciteck Clinical Laboratories
317 Rutledge Road
Fletcher, NC 28732

To the Responsible Person:

This letter is to advise Sciteck Clinical Laboratories (Sciteck) that the Division of Workplace Programs (DWP), a component of the Substance Abuse and Mental Health Services Administration (SAMHSA) in the Department of Health and Human Services (HHS), has revoked the laboratory's certification to conduct drug testing under section 3.13 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). See 69 FR 19644-19673 (April 13, 2004).

SAMHSA notified Sciteck of the immediate suspension and proposed revocation of the laboratory's certification on November 14, 2005. Accordingly, the proposed revocation would take effect 30 days after receipt of the notice, or if a review was requested, upon the reviewing official's decision to uphold the suspension or proposed revocation. Notice of the suspension was published in the Federal Register in accordance with section 3.15(e) of the Mandatory Guidelines. See 70 Fed. Reg. 73019, December 8, 2005. On November 21, 2005, Sciteck petitioned the United States District Court for the Western District of North Carolina for a temporary restraining order and preliminary injunction. The Court initially granted a temporary restraining order, and conducted a hearing on November 29, 2005, on Sciteck's motion for a preliminary injunction. As you are probably aware, in an order dated December 1, 2005, the Court denied Sciteck's motion for a preliminary injunction, vacated the temporary restraining order, and dismissed the case. The court's dismissal of the case established the grounds for SAMHSA to continue the suspension and proposed revocation of the laboratory's certification in accordance with the notice issued on November 14, 2005. See civil case number 1:05CV346 for the U.S. District Court for the Western District of North Carolina Asheville Division, 2005 WL 3277998.

On December 13, 2005, your attorney, Mr. James Gary Rowe, notified SAMHSA of Sciteck's request for review of the suspension and proposed revocation of Sciteck's certification to engage in urine drug testing for Federal agencies under the Mandatory Guidelines issued by the Department of Health and Human Services (69 Fed. Reg. 19644, April 13, 2004). As set out in the review procedures (Subpart D of the Mandatory Guidelines), Sciteck and the respondent, SAMHSA, had 15 days from the receipt of the acknowledgment letter to submit a review file and written statement to the reviewing official. SAMHSA's brief was submitted on January 5, 2006. The reviewing official granted an extension of time to Sciteck to file the necessary documents. On February 8, 2006, the reviewing official issued a final decision upholding the decision by SAMHSA to

suspend Sciteck's certification to perform urine drug testing in the Federal Workplace Drug Testing Program as set forth in the Mandatory Guidelines.

The revocation is based on the laboratory's lack of an approved Responsible Person (RP) and other deficiencies as identified in earlier written correspondence and reports of site visits as summarized below. The laboratory's designated RP failed to fulfill the requirements for an individual to serve as RP of a certified laboratory as specified by section 2.3 of the Mandatory Guidelines. The additional RP candidate proposed by the laboratory was not found fully acceptable to serve as the RP. The deficiencies identified prevent Sciteck Clinical Laboratories from ensuring the reliability and accuracy of its drug testing and reporting. The deficiencies are material and the revocation is required to protect the interests of the United States and its employees and to protect the public health and safety.

Reasons for Proposed Revocation

SAMHSA suspended the laboratory's certification on November 15, 2005, and proposed revocation of the laboratory's certification based upon unsatisfactory performance in the last three laboratory inspections (including the last inspection conducted on August 25-26, 2005). The serious deficiencies identified in the operation of the laboratory affect Sciteck Clinical Laboratories' ability to ensure the full reliability and accuracy of drug testing and reporting. See the Mandatory Guidelines, section 3.13 (a) and (b) (2) and (5). The deficiencies identified are material and the revocation of certification is required to protect the interest of the United States and its employees and to protect the public health and safety.

The following serious deficiencies were identified at prior inspections:

1. Responsible Person Evaluations

At the time of the third maintenance inspection in December 2004, the RP was acting pursuant to a previous determination that he was "conditionally" approved as RP. He had been interviewed and evaluated at two previous on-site inspections (i.e., the Special NLCP Inspection of April 13, 2004, and the laboratory's second NLCP maintenance inspection of June 17-18, 2004) and had not been found fully acceptable. He was conditionally approved following those inspections, because he was found to be deficient in specific areas but was judged by inspectors to be capable of functioning as the RP for a limited time while correcting the deficient areas. During the December 2004 inspection and the April 2005 Special Inspection, he was found unacceptable as the RP. The NLCP notified the laboratory of the RP issues in separate correspondence following each of these inspections. DWP/SAMHSA/HHS allowed the laboratory to continue to function under his direction as a conditional RP until the fourth maintenance inspection conducted on August 25-26, 2005. DWP/SAMHSA/HHS notified the laboratory that the RP or another RP candidate must be found fully acceptable as the RP at the fourth maintenance inspection.

During interview by the inspection team at the fourth maintenance inspection (August 25-26, 2005), the RP failed to demonstrate the ability to assess the adequacy of both the administrative and analytical aspects of the data. The RP failed to demonstrate a detailed, working knowledge of the following:

1. Analytical procedures for initial drug tests

   The RP was not fully familiar with calibration procedures. He did not know the level of imprecision that caused a calibration error flag.

2. Analytical procedures for confirmatory drug tests

   The RP was not fully familiar with all aspects of the laboratory's data package and confirmation testing procedures. He incorrectly described the criteria for GC/MS instrument tunes. He incorrectly identified the ions produced by the fragmentation process as isotopes. He was not fully familiar with GC/MS peak resolution criteria specified by the program. He could not describe how the confirmation test analyte for marijuana metabolite (i.e., delta-9-tetrahydrocannabinol carboxylic acid) was altered by derivatization.

Based on the deficiencies outlined above, the RP does not have the minimum scientific qualifications in analytical forensic toxicology specified by section 2.3 of the Mandatory Guidelines. Specifically, the RP is not certified by the State in forensic or clinical laboratory toxicology in accordance with section 2.3(a)(2)(i), does not have a Ph.D. in one of the natural sciences with specified coursework in accordance with section 2.3(a)(2)(ii), and did not demonstrate that he has the alternate acceptable scientific qualifications of "training and experience comparable to a Ph.D., in one of the natural sciences" specified in section 2.3(a)(2)(iii). The RP did not meet the requirements of section 2.3(a)(2)(iv)(B) in that he did not demonstrate knowledge evidencing appropriate training and/or experience in forensic applications of analytical toxicology to qualify him as an expert witness in forensic toxicology. He was judged to be unqualified to serve as an RP "to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility" as described in section 2.3(a)(1).

The RP failed to fulfill all responsibilities of the RP position described in section 2.3 of the Mandatory Guidelines. The following issues were identified during the fourth maintenance inspection (August 25-26, 2005):

1. The RP failed to ensure that the Standard Operating Procedures (SOP) manual was complete, up-to-date, available, and followed by laboratory personnel as required in section 2.3(a)(5).

   - The SOP did not adequately describe some procedures and some procedures were not consistent with laboratory practice.

   - The RP had not reviewed, dated, and signed each section of the SOP annually in accordance with program guidance.

2. The RP failed to establish a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining qualify control (QC) testing; and for assuring and documenting the validity, reliability, accuracy, precision,

and performance characteristics of each test and test system as required in section 2.3(a)(6).

- The RP failed to ensure that all QC samples used in regulated testing were properly verified, documented, and labeled. The SOP did not include procedures for preparing some QC samples and the preparation of some QC samples was not documented.

- The RP failed to obtain certificates of analysis from the supplier to document that all purchased calibrators and controls were prepared using pure drug reference materials in accordance with program guidance.

- Information on the labels of some QC samples was incorrect and/or not consistent with laboratory QC records.

- The RP failed to document the isotopic contribution from all internal standards used in regulated testing in accordance with program guidance.

- The RP failed to ensure that all control results were properly documented. There was no evidence of the RP's review of the cumulative records for some controls.

3. The RP failed to ensure that all remedial actions necessary were taken to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being with performance specifications and in response to issues identified in the inspection and performance testing phases of the NLCP as required in section 2.3(a)(7).

    - The RP failed to address all issues raised during the third maintenance inspection and the April 2005 Special Inspection.

    - At the time of the fourth maintenance inspection on August 25-26, 2005, the RP failed to initiate an investigation and corrective action to address all errors in NLCP PT occasion 75, cited in August 8, 2005, correspondence to the laboratory.

Therefore, this RP failed to demonstrate adequate knowledge of the laboratory's procedures and/or of the HHS Guidelines, and failed to demonstrate acceptable performance as an RP of a certified laboratory on five consecutive inspections. He has not fulfilled the requirements for an RP as specified in section 2.3 of the Mandatory Guidelines.

The additional RP candidate proposed by the laboratory did not meet the requirements of section 2.3(a)(2)(iv)(B) in that he failed to demonstrate knowledge evidencing appropriate training and/or experience in forensic applications of analytical toxicology to qualify him as an expert witness in forensic toxicology. At the time of the fourth maintenance inspection (August 25-26, 2005), he was judged to be unqualified to serve as the RP of the laboratory, "to assume professional, organizational, educational, and administrative responsibility for the laboratory's

urine drug testing facility" as described in section 2.3(a)(1). The following issues were identified during the inspection:

1. The additional RP candidate had limited on-site training at the laboratory and had not been trained as a certifying scientist for the laboratory.
2. The additional RP candidate had limited GC/MS experience (i.e., the analytical method used for confirmatory drug testing).
3. The laboratory had failed to develop a specific schedule for the amount of time the additional RP candidate would spend on-site as an RP should he assume RP duties.

These personnel deficiencies are extremely serious because they bring the forensic and scientific supportability of test results into serious doubt. The RP is critical in ensuring the full reliability of the drug test results (Section 2.3). The unsatisfactory performance of the conditional RP and additional RP candidate required the government action of suspension and proposed revocation of the laboratory's certification.

2. Security

The laboratory did not properly document individuals with authorized access to the long-term storage freezer where regulated specimens were maintained and did not limit access to only authorized personnel.

First, the laboratory did not maintain an access roster for the long-term specimen storage freezer as required by section 2.4(a)(1) of the Mandatory Guidelines.

Second, one individual who did not have responsibilities related to regulated specimens had access to the key to the long-term specimen storage freezer. This is not in accordance with section 2.4(a)(1) of the Mandatory Guidelines.

The security of specimens is of major concern in forensic workplace drug testing programs. The laboratory's failure to properly document individuals with authorized access to the secured specimen storage freezer and the laboratory's failure to limit access only to authorized personnel are serious deficiencies.

3. Quality Control Materials and Reagents

First, the laboratory did not have a written procedure for the preparation of some initial drug test controls (i.e., controls at 75% and 125% of the cutoff). The RP indicated that he had the information in his personal notes and provided a typed copy of the procedure when this issue was raised during the inspection.

Second, the laboratory did not have a record of the preparation of some initial drug test controls (i.e., controls at 75% and 125% of the cutoff). The RP indicated that he had the information in his personal notes and provided a typed copy when this issue was raised during the inspection. The information provided contained an incorrect statement concerning the amphetamine result for the positive control (i.e., 125% of the cutoff) during verification.

Third, the laboratory did not have a copy of the certificate of analysis for each control lot in use. When it was noted that the information on the labels of the negative urine control and the "SVT I control" was not consistent with QC records, it was discovered that the laboratory did not have the certificates of analysis for the current lots of these materials.

Fourth, the laboratory had not documented the lack of contribution from the deuterated internal standard solution to the native (non-deuterated) drug when verifying internal standards for confirmatory drug tests as required by the program. This issue was raised during the remediation process following the third maintenance inspection and was cited in the April 2005 Special Inspection. Although it was noted that the laboratory had revised the SOP for internal standard verification prior to the inspection, the laboratory had not documented the isotopic contribution of all internal standards in use for regulated specimens.

Fifth, the laboratory had not verified the concentration of amphetamine in the positive threshold initial drug test control (i.e., 125% of the cutoff) in use during the inspection. The RP indicated that the initial preparation of the control did not meet laboratory acceptance criteria for amphetamine (i.e., the result was less than the cutoff). The RP indicated that, in response to the amphetamine result, the control material was fortified with additional drug standard material. Upon reanalysis, the control material met immunoassay acceptance criteria for amphetamine, but the concentration was not verified as specified in program guidance (i.e., page G-4 of the NLCP Guidance Document for Laboratories and Inspectors, November 2004).

Sixth, the laboratory had not properly verified all controls prior to placing them into service. The laboratory prepared the conjugated THCA control from pooled donor specimens and used the control to monitor the effectiveness of the hydrolysis step in the extraction procedure. During verification, the laboratory did not analyze the control with and without the hydrolysis step to document the presence of glucuronide.

Seventh, the labels on all controls that were in use during the inspection did not contain correct information. The GC/MS positive controls in use (QAS lot number 04055949) listed an expiration date of May 2005. The laboratory had documentation from the manufacturer indicating that the expiration date had been extended to December 2005, but the labels on the containers had not been updated to reflect this change.

Eighth, the laboratory did not document the GC/MS batch in which a new reagent was first used, as part of the reagent verification record. This is not consistent with program guidance (i.e., page G-9 of the November 2004 NLCP Guidance Document for Laboratories and Inspectors).

It is essential to document the use of acceptable QC materials and to verify each QC sample, reagent, and internal standard lot prior to placing it into service. These requirements are addressed in sections 2.3(a)(6), 2.4(q)(1), and 2.4(q)(2) of the Mandatory Guidelines and in the November 2004 NLCP Guidance Document for Laboratories and Inspectors (section G). The use of unacceptable QC materials or internal standards can lead to inaccurate specimen results (i.e., false positive and false negative test results), as well as test results that are forensically unsupportable. This is contrary to the interests of the United States in protecting public health and safety and its employees.

4. Quality Assurance

The laboratory had quality assurance (QA) procedures in place for documenting control failures in the initial drug and specimen validity tests and for reviewing the cumulative results to allow identification of instrument or assay problems, in accordance with the NLCP Guidance Document for Laboratories and Inspectors (page H-1). However, laboratory staff did not consistently follow the procedures.

First, there were discrepancies between lot numbers of controls that were in use and the lot numbers listed on the QC charts (e.g., the benzoylecgonine control at 40% of the cutoff).

Second, staff did not record all control results. Some failed QC results identified on corrective action sheets had not been plotted on the QC charts (e.g., the methamphetamine positive control analyzed on August 15, 2005, the amphetamine/methamphetamine positive control analyzed on July 26, 2005).

Third, the RP did not sign the QC charts to document his review of cumulative initial drug test control results. Therefore, there was no evidence that the RP had reviewed the records as required by the laboratory's SOP.

It is the responsibility of the RP to maintain a QA program to assure the proper performance of all test results and to maintaining acceptable analytical performance of all controls and standards as specified by section 2.3(a)(6) of the Mandatory Guidelines. An essential part of the QA program is the RP's review of cumulative control results, including results of failed controls, as described in the NLCP Guidance Document for Laboratories and Inspectors (page H-2).

5. Equipment and Maintenance

First, the laboratory had not complied with the maintenance schedule recommended by the manufacturer of the immunoassay instruments. The laboratory used manufacturer-provided charts for documenting instrument preventive maintenance. Although daily and weekly maintenance activities were documented, some monthly and quarterly maintenance activities were not performed. Laboratory staff indicated that some maintenance activities were performed "as needed" instead of at the intervals specified on the charts. However, maintenance procedures and charts had not been revised to reflect laboratory practice.

Second, there was no evidence that staff had performed GC/MS maintenance in accordance with the laboratory's SOP. The laboratory had developed GC/MS maintenance logs that listed specific weekly tasks. Staff had not documented the weekly tasks since August 3, 2005.

Third, it was unclear whether the laboratory had maintained proper storage conditions for regulated specimens in the long-term specimen storage freezer. The freezer did not have a mechanism to continuously monitor temperature. Personnel were present to document the temperature Monday through Friday of each week. The following issues were raised:

- Entries on the temperature log for the long-term storage freezer on August 11, 12, and 19, 2005, were not -20 degrees Celsius or less as specified in Section 2.4(i) of

the Mandatory Guidelines. There were no entries in the comments section of the temperature log to indicate that laboratory staff identified and took corrective actions in response to these instances.

- Moisture was observed on the floor in front of the long-term specimen storage freezer. In addition, a bucket was observed behind the freezer. The RP was asked whether the freezer had a self-defrost mechanism, but he did not know.

Fourth, the laboratory had a generator to provide back-up power in the event of a prolonged power failure. The SOP did not include a procedure for periodically verifying and documenting that the generator functioned as expected, to ensure proper storage conditions of specimens.

6. Specimen Validity Tests

First, the RP provided the inspectors with updates to material submitted to the NLCP prior to the fourth maintenance inspection. Some updated information (e.g., comments included on the custody and control form for reporting specimens adulterated due to pH; acceptance ranges for some QC samples) was not consistent with the laboratory's SOP and QC records.

Second, during the inspection, staff did not take corrective action when creatinine results for several specimens exhibited error flags with numerical results less than zero (Limit 0 errors). The immunoassay analyst indicated that corrective actions were not routinely taken in those instances. The practice did not comply with the SOP requirement to reanalyze specimens with Limit 0 error flags.

It is the responsibility of the RP to take all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to QC systems not being within performance specifications as specified by section 2.3(a)(7) of the Mandatory Guidelines, and to ensure that personnel follow the laboratory's SOP as specified in section 2.3(a)(5) of the Mandatory Guidelines. Furthermore, section 2.4(q)(4) of the Mandatory Guidelines requires each certified laboratory to document that corrective actions have been taken in accordance with written procedures, and to have systems in place to verify that the procedures are followed.

7. Confirmatory Drug Tests

Material submitted to the NLCP prior to the fourth maintenance inspection and the laboratory's SOP indicated that QC results were required to be within 20% of the target value. In practice, QC results were required to be within 20% of the assayed mean.

8. Standard Operating Procedures

First, all procedures were not appropriately described in the laboratory's SOP, as required by sections 2.3(a)(5) and 2.4(q)(1) of the Mandatory Guidelines. Some procedures were not included in the SOP and some procedures in the SOP did not accurately reflect practice.

Second, the RP had not reviewed, dated, and signed each section of the SOP on an annual basis in accordance with program guidance (i.e., page N-3 of the NLCP Guidance Document for Laboratories and Inspectors, November 2004).

It is the RP's responsibility to ensure that the laboratory's procedure manual is complete, up-to-date, and followed by laboratory personnel, as specified in section 2.3(a)(5) of the Mandatory Guidelines.

9. Personnel

First, as noted under "Responsible Person Evaluation" above, the RP failed to demonstrate adequate knowledge of the laboratory's procedures and failed to demonstrate acceptable performance as an RP of a certified laboratory.

Second, the RP served as a non-negative certifying scientist. He did not demonstrate a detailed, working knowledge of the laboratory's procedures for initial drug tests and confirmatory drug tests. This is not consistent with the requirements for a certifying scientist as specified by sections 1.2 and 2.3(b) of the Mandatory Guidelines.

The observed deficiencies call the forensic and scientific supportability of the laboratory's test results into serious doubt.

10. NLCP Performance Test (PT) Records

At the time of the inspection, the laboratory had not initiated investigative and corrective actions in response to NLCP PT errors for which the laboratory was not required to submit a remedial report (i.e., a benzoylecgonine quantitation error and a large number of clerical errors identified in NLCP PT occasion 75 as specified in program correspondence of August 8, 2005).

Summary

The deficiencies listed above prevent Sciteck Clinical Laboratories from ensuring the full reliability and accuracy of its drug testing and reporting. These deficiencies show a serious failure by Sciteck Clinical Laboratories to conduct employee drug testing using good forensic laboratory practice as required by the Mandatory Guidelines. These deficiencies require the revocation of Sciteck Clinical Laboratories' certification in order to protect the interests of the United States and its employees.

The Period of Revocation

The revocation of Sciteck's certification was effective on February 8, 2006, the date the reviewing official upheld SAMHSA's suspension and proposed revocation of Sciteck's certification. (See Section 3.15 of the Mandatory Guidelines, "Effective Date"). In accordance with the Mandatory Guidelines, sections 3.13 (c) and 3.16, the period of revocation shall continue for not less than 12 months from its effective date. At the conclusion of this period, the laboratory may apply for certification as an applicant laboratory. Notice of this revocation will be published in the Federal Register. In addition, this is to inform you that, as a result of the suspension and revocation of the laboratory's certification, you are no longer entitled to

advertise to the public that Sciteck Clinical Laboratories is certified by SAMHSA/HHS under the National Laboratory Certification Program (NLCP) for urine drug testing performed in accordance with the requirements of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 Fed. Reg. 19644-19673, April 13, 2004).

If you have any questions regarding this revocation, please call Dr. Donna Bush at (240) 276-2602.

Sincerely,

/signed/

Robert L. Stephenson II, M.P.H.
Director
Division of Workplace Programs

cc: Constance Foster, HHS, Office of the General Counsel
Rina Hakimian, HHS, Office of the General Counsel
Paul Taylor, Assistant US Attorney, Western District of North Carolina
Dr. John M. Mitchell, RTI International
Dr. Michael R. Baylor, RTI International
Jack Smith, CEO, Sciteck Clinical Laboratories
J. Gary Rowe, Attorney