U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Soft Computer Consultants, Inc. 4/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4770

VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

WARNING LETTER
FLA-15-23
April 30, 2015

Mr. Gilbert Hakim, CEO
Soft Computer Consultants, Inc.
5400 Tech Data Dr.
Clearwater, FL 33760

Dear Mr. Hakim:

During an inspection of your establishment located in Clearwater, FLon January 5-15, 2015, investigators from the United States Food and Drug Administration (FDA) determined that your firm

manufactures Class I/II software systems. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. § 321(h)], these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

These violations include, but are not limited to, the following:

1. Failure to adequately establish procedures for CAPA as required by 21 CFR 820.100(a). Specifically,

A. Product Change Controls (PCCs) which are corrective and preventive actions for handling software coding defects do not always include investigating the cause of all nonconformities relating to product, processes and the quality system, and identifying action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems. For example;

i. PCC-54168 dated 4/25/14 was a CAPA for investigating a software defect in **(b)(4)** for clients using the Results Reporting interfaces to send results to an **(b)(4)** or **(b)(4)** system. The defect was that the interface fails to send the abnormal flags for Reference Lab test results. This affects the flag that indicates the result is abnormal. Caregivers, who rely on the abnormal flag rather than the results may come to an incorrect conclusion. The PCC-54168 identified a software coding error as the assignable cause of this problem. Your firm also identified that the software interface between your software and other software was not fully tested. A mandatory software Hot Fix was created due to the severity of the failure mode. The mandatory Hot Fix led to a correction and removal (1058332-10/13/2014-002-C). This PCC did not include the following:

a. An analysis to determine if other software products manufactured have had similar failure modes due to lack of testing of software interfaces.

b. Software testing that was created for verifying this corrective action was not included in the repository of tests known as **(b)(4)** tests as required by your **(b)(4)** Testing Procedure, SOP TST_P005, to allow these tests to be run for future software changes.

ii. PCC-52730 dated 12/31/13 was a CAPA for investigating a software defect in **(b)(4)** version **(b)(4)** when used with **(b)(4)** version **(b)(4)**. The problem was that when an isolate is resulted without a SNOWMED code, the isolate information in the downstream system may be incomplete or missing. As a result, there is a potential for the delay or omission of patient treatment updates. Your firm identified a software error as the assignable cause of this problem. Your firm also identified that the software interface between the **(b)(4)** system and **(b)(4)** was not fully tested which would have identified the software defect. A mandatory software Hot Fix was created due to the severity of the failure mode. The mandatory Hot Fix

led to a correction and removal (1058332-10/13/2014-001-C). This PCC did not include the following:

a. An analysis to determine if other software products manufactured have had similar failure modes due to lack of testing of software interfaces.

B. Your firm is not analyzing all sources of quality data to identify existing and recurring quality problems. For example;

i. According to your Client Complaint – Medical Device Trending Analysis Procedure, SOP G01S1150 version 5.1, your firm is required to perform trend analysis **(b)(4)** of the complaint data and report the data to Executive Management at the Quality System Management Review meeting. Your firm has not conducted these trend analysis activities since 12/31/2012. The four **(b)(4)** trend analysis reports for 2013 and 2014 have not been generated.

ii. The trend analysis report for the complaint date range of 3/1/2012 through 12/31/2012 was created on or about 12/15/2014 and as of the close of the inspection on 1/15/2015 (approximately 2 years later) has still not been fully reviewed and approved and submitted to Executive Management at the Quality System Management Review meeting.

iii. Your firm is not analyzing the Product Change Control (PCC) tasks for identifying existing and recurring quality problems. The PCCs are one type of CAPA used by your firm for performing corrective and preventive action activities.

C. Your firm initiated a Field Correction, 1058332-11/28/2014-C, on 11/26/14 associated with **(b)(6)**. It appears that your firm has not validated the respective Hot Fix and that it is available for distribution for all affected customers.

2. Failure to adequately establish procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. Specifically,

A. Quality contracts for the design contractors (**(b)(4)** & the **(b)(4)**) who perform design of software do not include a provision that the design contractors agree to notify your firm of changes in the product code or service so that your firm may determine whether the changes may affect the quality of the product provided.

B. According to the VP of Administration and the VP of Genetics and Anatomic Pathology (AP) who are both responsible for conducting supplier audits of the contractors in **(b)(4)** and in the **(b)(4)**, the supplier audits of the facilities are reportedly to be conducted **(b)(4)**. The supplier audits are divided into two categories Administrative and Technical. Administrative audits covered reviewing the Quality contract, verifying employee training and experiences are suitable at the respective contract facilities. Technical audits include auditing design projects, adherence to design control requirements, and adherence to standard operating procedures. Review of the documents provided identified the following:

i. There is no documented evidence that Technical supplier audits for the **(b)(4)** contract facility were conducted for 2012 and 2013. The Technical supplier audit conducted for

September 2014 for the **(b)(4)** facility has not been reviewed or approved as required by your Conducting External Quality Audits Procedure, SOP AUD_P003.

ii. There are no corresponding Quality Audit Plans as required by SOP for any Technical supplier audits for the **(b)(4)** contracting facility for 2012, 2013, or 2014.

C. The following supplier audits were not reviewed in a timely manner and were not conducted by the Regulatory Analyst identified as the auditor:

type	facility	audit date	audit review date
Admin	**(b) (4)**	July-Aug '12	04/24/14
Admin	**(b) (4)**	Sept-Oct '12	04/24/14
Tech	**(b) (4)**	June-Aug '12 **	03/20/14
Tech	**(b) (4)**	Sept-Dec '12	03/20/14
Admin	**(b) (4)**	June-Sept '12	04/25/14

** There is no documented evidence that Technical audits were conducted in 2013.

D. According to your Conducting External Quality Audits Procedure, SOP AUD_P003, the Audit Topic Results Form and the supplier audit findings are to be presented for management review at scheduled management review meetings based on your Executive Management Quality System Review Procedure, SOP1112. These activities have not been conducted for any of the supplier audits of the **(b)(4)** and **(b)(4)** facilities.

3. Failure to establish and maintain procedures for design change, as required by 21 CFR 820.30(i). Specifically,

A. The software changes made by your firm and the **(b)(4)** and **(b)(4)** contractors are not assessed by your firm to confirm that the design changes meet their intended use and conform to all of your requirements including all verification and validation activities. The following are examples:

i. The Hot Fixes used to correct design defects for **(b)(6)** that were part of the correction and removal submitted to FDA on or about 12/10/14. The software changes were made by the **(b)(4)** contractor.

ii. The Hot Fixes used to correct design defects for **(b)(6)** that were part of the correction and removal submitted to FDA on or about 11/4/14. A portion of the software changes were made by the **(b)(4)** contractor.

iii. The Hot Fixes used to correct design defects for **(b)(6)** that were part of the correction and removal submitted to FDA on or about 2/17/14. The software changes were made by your firm.

B. User requirements (design inputs) are not required by either your firm or any of your contracting organizations for any software custom scripts created that can be used as part of a software Hot Fix (software correction made to a customer). Hot fixes are used as an emergency or high priority change that needs to be made when the client or your firm cannot wait for the normal patch process for any product manufactured by your firm.

For example, the Hot Fix utility used to identify the design defects for **(b)(6)** did not include documentation of user requirements (design inputs) for the Hot Fix utility 1.18021.1. This Hot Fix utility for the **(b)(4)** software was used to identify defective records in the customer's database and was a part of the correction and removal submitted to FDA on or about 12/11/14. Your Hot Fix Process, SOP G01D072, does not include any requirements for documenting design inputs for custom scripts.

4. Failure to establish and maintain procedures for design review as required by 21 CFR 820.30 (e). Specifically,

There was no evidence to demonstrate that the Release notes for Hot Fix utility 1.18021.1 used to identify defective records in the customer's database for software package **(b)(4)** were reviewed and approved. Under section 5.2d of your Release Note Processing Workflow Procedure, G04S1082, the product specialist or designee is required to review the release notes and place them in the published status prior to going live (release). This Hot Fix utility was part of a correction and removal submitted to FDA on or about 12/11/14. The Release notes are provided to the customer or your personnel for all software changes

5. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. Specifically,

A. Your Preparing for Conducting Internal Audits Procedure, AUD_P001, and Audit Approval Procedure, AUD_P002, does not include specific information regarding how to conduct the audits. For example; the procedures do not specify what records need to be reviewed, the quantity of records to review, and what the criteria is for acceptance or failure.

B. The employees who perform quality audits were not trained on the current revision of your Audit Approval Procedure, AUD_002, before they conducted Quality Audits. Version 2.0 of this procedure was effective 11/04/2013. There are (b) (4) employees performing quality audits who were not trained on Version 2 of the procedure until after they conducted quality audits and did not receive the training until after the FDA inspection was initiated. One of these quality auditors has yet to receive the training.

6. Failure to establish and maintain procedures to ensure that the devices are designed and produced as required by 21 CFR 820.20(b). Specifically, adequate and appropriate resources have not been allocated to perform quality related functions required by your firm's quality system. For example;

A. According to your SOP G01S1150 version 5.1, your firm is required to perform trend analysis **(b)(4)** of the complaint data and report the data to Executive Management at the Quality System Management Review meeting. Your firm has not conducted these trend analysis activities since 12/31/2012. The four **(b)(4)** trend analysis reports for 2013 and 2014 have not been generated.

B. The Technical supplier audits of the **(b)(4)** design contractor were not conducted for 2012 and 2013. The Technical supplier audits of the **(b)(4)** design contractor were not conducted for 2013.

We received responses from Gilbert Hakim, CEO dated February 3, 2015, February 16, 2015 and March 2, 2015 concerning the investigators' observations noted on the Form FDA 483 (FDA 483), Inspectional Observations, which was issued to your firm. Your responses did not provide adequate supporting evidence that the referenced corrections and planned courses of action have been implemented.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Please send your reply to the U.S. Food and Drug Administration, Attention: Andrea H. Norwood, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, FL 32751. If you have any questions regarding any issues in this letter, please contact Ms. Norwood by telephone at (407) 475-4724.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Susan M. Turcovski
Director, Florida District